

Study on the properties of NR latex-Nanosilica composite for surgical gloves

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Abstract

Surgical gloves are intended as a barrier between the patient and the healthcare worker. This paper deals with the study conducted on natural rubber based surgical gloves incorporated with Nanosilica. Nanosilica was incorporated into NR latex and then compounded with regular cure ingredients typical of a glove formulation. The compounded latex was then dipped in suitable moulds of ceramic material and processed by conventional method in a continuous chain surgical gloves dipping line. All the parameters of a glove production line were simulated in the production of surgical gloves, used in the study. The water soluble residual protein content and the physical properties of the glove were studied. . Presence of water soluble residual proteins sensitizes the human body and hence it's presence is an issue in the manufacture of Surgical gloves. It was observed during the study that there was considerable reduction in protein content on addition of nanosilica but the physical properties of the glove remained unaffected. A dosage of 0.1 to 0.5 phr of Nanosilica on rubber was used and the properties were found to be optimum at 0.2 phr levels. The study revealed the possibility of reduction in protein content by incorporating Nanosilica.

Key words : natural rubber latex, nanosilica, surgical gloves, nanocomposites, latex proteins

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1.0 INTRODUCTION

Medical gloves are disposable gloves used during medical examinations and procedures that help prevent contamination between caregivers and patients. Medical gloves are made of different polymers, the most popular being natural rubber, Polyisoprene, Neoprene and Nitrile rubber. The choice of most surgeons is of course natural rubber, which provides excellent tactile sensitivity and comfort [1]. Latex material is known

to have a very high elasticity making the glove stretch well to allow easy donning, but it contains certain proteins that can sensitize the human body. The latex protein allergy affecting some users of latex products has caused great concern to both the medical profession and the latex product industry [1,2,3]. A protein value of 50 µgm/dm² is the sensitivity limit for the ASTM modified Lowry test method for residual proteins [3] and is considered to be the threshold value for sensitization of humans. Since it is difficult to reduce

the residual proteins to this level in a glove production line, an offline washing method is often resorted to. Some studies have been made using Fumed silica for reduction of residual proteins but difficulties in handling and incorporation along with the high cost of Fumed silica has often deterred its use in commercial glove production [4]. This study is intended to explore the possibility of using Nanosilica, in liquid phase, to reduce the residual protein content to below threshold levels, on a glove production line, thereby reducing the necessity of an offline washing process. The physical properties of the Nanosilica – NR composite were also studied.

2.0 MATERIALS

Centrifuged latex containing 60% dry rubber content was used in the study. The compounding ingredients were prepared in a pearl mill. The dispersion was prepared as a 40% composite dispersion containing all the compounding ingredients ground into slurry. The stabilizer Potassium Hydroxide was prepared as a 10% solution in water. Nanosilica, NANOSIL-T was obtained from M/s BEECHEM as a 30 % dispersion. Fresh centrifuged latex was purchased from M/s Njavallil latex, Cochin. All the raw materials were tested in the laboratory and passed all Quality Assurance tests qualifying it to be used in a glove production process.

3.0 EXPERIMENTAL

3.1 Characterization of Nanosilica

The Nanosilica was characterized by SEM and the particle size was found to be in the range 50 – 70nm (*Fig 01*). The elemental analysis shows the presence of Si and O, confirming the presence of SiO₂. (*Fig 02*).

3.2 Incorporation of Nanosilica

Nanosilica was incorporated into the latex compounds by two methods.

3.2.1 Method I: Adding Nanosilica into pre-compounded latex,

Nanosilica was added into the ready-to-feed compounded latex. The ready-to-feed compounded latex was pre-mixed with all the necessary compounding ingredients (*Table 01*) and matured to a level optimal to feeding into the production line. This method was tried out due to the easiness in incorporating the method into a regular glove manufacturing process.

A typical formulation for a surgical glove is given in *Table 01*. Varying dosages of Nanosilica dispersion at 0.1, 0.2, 0.3, 0.4 and 0.5 phr was added to compounded latex, formulated as per *Table 01*.

The gloves were made on the dipping machine simulating all the process parameters of a regular glove production process. The control was taken as the regular glove, without Nanosilica, produced on the machine during the experimental run. The gloves with varying dosages of Nanosilica were tested for residual protein content and physical properties. The properties were compared to regular gloves produced during that period.

3.2.2 Method II: preparing a latex compound after incorporating Nanosilica into raw latex,

Nanosilica was added into the raw latex, matured the mixture for a known period of time and then compounded with chemicals, as per common practice. Varying parts of Nanosilica was added to raw latex and the effect of Nanosilica on the raw latex properties was studied. The Nanosilica incorporated latex compound was then used to manufacture surgical

gloves.

Nanosilica dispersion, diluted to 15%, with distilled water, was added to the centrifuged latex. Sample latex batches containing 0.1, 0.2, 0.3, 0.4 and 0.5 parts of Nanosilica were prepared. The mixture was kept stirred, for aging, at room temperature. Samples were drawn from the mixture soon after mixing and after regular intervals of 1 week, 2 weeks, 3 weeks and 4 weeks. The properties of the Nanosilica filled latex compound was studied with reference to unfilled raw latex properties. Films were cast from the mixture and residual protein content was determined, after each interval. The aged latex – Nanosilica mixture was then compounded with rubber chemicals. The compounded latex was then matured and dipped to produce surgical gloves. The gloves were tested for residual proteins and tensile strength.

4.0 RESULTS AND DISCUSSION

4.1 Characterization of Nanosilica

Characterization of Nanosilica showed the presence of SiO₂ in the nanoparticle size range of 50 – 70 nm. The 30% Nanosilica dispersion is a mildly turbid solution of pH 11.5.

4.2 Method I : study on properties after adding Nanosilica into pre-compounded latex,

The tensile properties on the glove samples were done as per ASTM D 412 and the aging properties as per ASTM D 573. The data on the tensile properties shows no considerable effect on the physical properties in comparison to the control sample i.e. Sample with no Nanosilica. The trend line analysis shows a minor decrease in 'before aging' and 'after aging' tensile properties with Nanosilica loading. The 'elongation at break' shows a minor

increasing trend in aged and unaged conditions. The trend however is not significant. The ANOVA statistical analysis shows that the differences observed in the values of mean are not significant and are simply due to random sampling error.

Natural rubber is a self crystallizing polymer and hence reinforcement effects by fillers are generally not observed to have an effect on it [6]. The observed values and trend in Physical properties is in agreement with the expected results.

The residual protein results are also found to be unaffected by the addition of Nanosilica. The values are erratic and do not follow any particular trend. Therefore it is observed that the addition of Nanosilica into pre-compounded latex does not give any improvement in reduction of residual proteins.

Nanosilica reacts or bonds preferentially with the compounding ingredients and gets inactivated thereby losing the ability to bind or coagulate protein molecules present in the latex. Therefore addition of Nanosilica to pre-compounded latex has negligible effect on the properties of the latex product

4.3 Method II - study on properties of a latex compound made from Nanosilica filled raw latex

4.3.1 Effect of maturation on Nanosilica - centrifuged latex mixture

Nanosilica was added to fresh centrifuged latex at 0.1, 0.2, 0.3, 0.4 and 0.5 parts on rubber. The properties of the initial mix with varying amounts of Nanosilica , are given in *Table 02*.

The mixes were matured for varying periods viz , 1 week, 2 weeks, 3 weeks and 4 weeks. The latex characteristics were studied after each period.

4.3.1.1 Effect of aging on DRC

It is observed that on addition of Nanosilica into the latex there is a tendency to form microlumps. This is observed only during the initial addition and DRC remains fairly constant on ageing the latex mix. This microlump formation may be due to the higher surface activity of the Nanosilica thereby agglomerating latex particles. This is more pronounced at higher concentrations and hence the DRC is found to reduce marginally on increased Nanosilica concentration but remains constant on ageing for 4 weeks.

4.3.1.2 Effect of aging on pH

pH is found to remain almost constant on addition of Nanosilica and has no effect on aging.

4.3.1.2 Effect of aging on coagulum

The increase in coagulum follows fairly the decreasing trend of DRC. Coagulum content is found to increase with Nanosilica concentration and aging period.

4.3.1.3 Effect of aging on KOH number

A marginal increase in KOH number is found with increased Nanosilica concentration. This marginal increase does not have any significant effect on the processing of latex. The curve steps after 0.2 parts. Aging has no significant effect on the values.

4.3.1.4 Effect of aging on VFA

No significant difference in values of VFA was observed with increased Nanosilica concentration.

4.3.1.5 Effect of aging on MST

A characteristic increase in MST with aging was observed in regular compound. This is due to the increase in stability due to formation of fatty acid soaps during storage. It is observed that the natural increase in MST expected on storage is reduced due to the addition of Nanosilica. This retarding effect is higher at higher concentrations of Nanosilica

4.3.1.6 Effect of aging on viscosity

Viscosity is found to be constant for concentrations up to 0.2 parts but keeps increasing after that. The latex becomes thicker, at higher concentrations, making further processing difficult. This increase in viscosity is attributed to the transfer of stabilizing ions from the surface of the latex into the smaller Nanosilica particles thereby destabilizing it. This destabilization of the latex particles results in increased viscosity.

The latex properties show only marginal differences for concentrations up to 0.2 parts and higher variations are shown at higher concentrations. The increase in latex viscosity results in difficulty for further processing of latex into products.

The viscosity was found to increase on keeping the latex and was found higher in 0.3, 0.4 and 0.5 parts Nanosilica filled compounds.

4.3.1.7 Effect of aging on the Extractable proteins

Water extractable protein content of the various mixes was determined, as per ASTM D 5712 method, from cast films of the latex mixes.

The protein content is found to reduce on increasing the Nanosilica dosage (*Fig 03*).

Proteins contribute to the overall stability of the latex and hence reduction of proteins could result in destabilization of latex. A slight destabilization of latex is observed at higher percentages as the coagulum content is found to increase with dosage.

Since the proteins undergo hydrolysis during compounding and processing of latex, the values of proteins at the raw latex stage may not be a true indication of the actual amount of proteins extractable after the product is made [5]. Hence study of extractable proteins at the product stage would be more appropriate.

4.3.2 Compounding of matured Nanosilica - centrifuged latex

From the above study on maturation of latex with Nanosilica, it was observed that the latex is stable, up to a month of storing, at 0.1 and 0.2 parts of Nanosilica. At higher concentrations the properties, especially the viscosity, was found to increase. The increase of viscosity, observed at higher concentrations, is considered to be a measure of instability of the latex.

The latex mixes were compounded with the regular compounding ingredients. The compounds were then matured for 48 hours under constant stirring. Before going in for production of gloves, films were cast from the mixes. The films of latex containing 0.3, 0.4 and 0.5 parts were found with small cracks and hence of low wet gel strength. Hence these mixes were found unsuitable for product manufacture. Unfilled compounded latex was kept as a control. The latex containing no Nanosilica, 0.1 and 0.2 parts Nanosilica was then used to produce surgical gloves. The process parameters were kept as per regular commercial production specifications. The gloves produced were conditioned and tested for physical properties and extractable residual proteins as per ASTM standards. *Table 03* and *Table 04* shows the

results of Tensile properties and Residual proteins, respectively.

The Tensile properties were found to be comparable with the control R and the retention of Tensile on aging was found better than the control. The control has retention of 85% whereas 0.1 parts showed retention of 90% and 0.2 parts 95%. The extractable proteins showed a reduction of 20% for 0.1 parts and 50 % for 0.2 parts. The viscosity was found to be suitable for further processing of latex.

5.0 CONCLUSION

- 5.1 Addition of Nanosilica to pre-compounded latex was found ineffective with respect to improvement in physical properties and reduction of extractable proteins.
- 5.2 Nanosilica was found effective when added to centrifuged latex and then compounded with chemicals
- 5.3 Considerable reduction in residual protein content was observed on addition of Nanosilica. This could help in the manufacture of low protein latex products from the production line and could avoid a time consuming and costly off line washing process. The reduction in proteins was observed to be around 20 % at 0.1 parts and around 50% at 0.2 parts.
- 5.4 The Nanosilica had the maximum effect at 0.2 parts per rubber without compromising on the tensile properties.

6.0 ACKNOWLEDGEMENT

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7.0 REFERENCES

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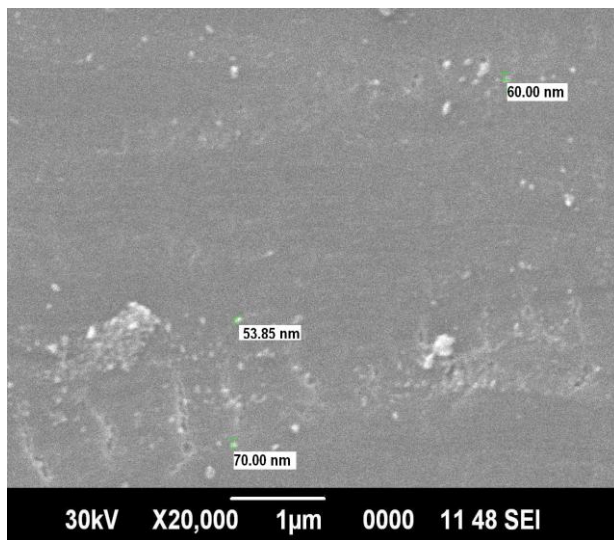


Fig 01: SEM of Nanosilica

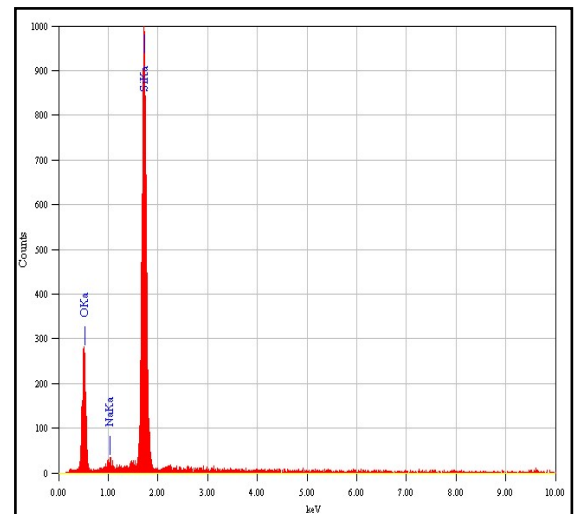


Fig 02: EDAX of Nanosilica

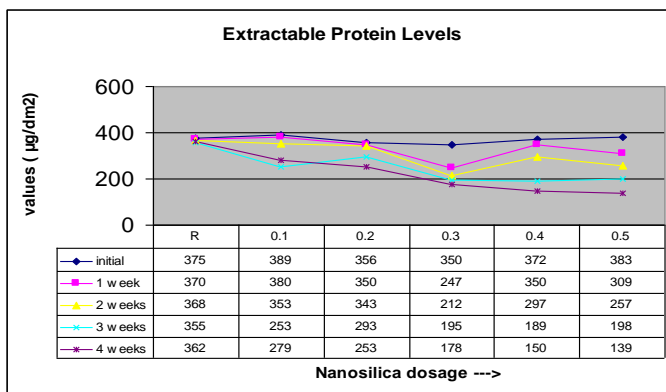


Fig 03: effect of aging on Extractable proteins

Ingredient	Parts
NR latex	167
Sulphur	1.0
Zinc oxide	0.5
ZDEC	0.75
ZMBT	0.25
Titanium oxide	0.25
Antioxidant (Wingstay L)	0.75
KOH	0.2
Dispersing agent	0.1

Table 01: A typical formulation for a surgical glove

Property	R	0.1	0.2	0.3	0.4	0.5
DRC	60.0	59.6	59.3	58.3	58.5	58.1
NRC	1.1	1.2	1.1	1.0	1.0	1.1
pH	11.0	11.0	11.1	11.1	11.0	11.1
TA	0.9	0.8	0.8	0.8	0.8	0.8
Coagulum	0.0	0.0	0.0	0.0	0.0	0.0
KOH	0.7	0.8	0.7	0.8	0.8	0.8
VFA	0.0	0.3	0.0	0.0	0.0	0.0
MST	695	691	701	709	710	725
Viscosity	25.0	25.0	25.0	25.0	25.5	25.5

Table 02: INITIAL – comparison of latex properties

<u>TYPE</u>	<u>TENSILE PROPERTIES</u>			
	<u>Before aging</u>		<u>After aging</u>	
R – control	26.4	798.0	22.0	700.0
A – 0.1 parts	25.9	805.0	23.3	725.0
B - 0.2 parts	29.3	812.0	28.0	710.0

Table 03: Tensile properties

<u>TYPE</u>	<u>RESIDUAL PROTEINS</u>
R – control	92.3
A – 0.1 parts	73.2
B - 0.2 parts	46.5

Table 04: Residual protein content

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Fig 03: effect of aging on Extractable proteins

Table 01: A typical formulation for a surgical glove

Table 02: INITIAL – comparison of latex properties

Table 03: Tensile properties

Table 04: Residual protein content