

Comparative Evaluation of Safety and Performance of Latex and Nitrile Surgical Gloves: A Post - Market Clinical Follow - Up Study

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Abstract: *Sterile Surgical Gloves are worn to prevent contamination of the patient during invasive procedures and they help prevent surgical site infections and reduce the risk of exposure to blood and body fluid pathogens for the healthcare worker. This post - market clinical follow - up study aimed to comprehensively evaluate and compare the safety and performance of three types of surgical gloves: Latex Surgical Gloves - Powdered, Latex Surgical Gloves - Powder Free, and Nitrile Surgical Gloves - Powder Free. Overall, 756 subjects participated in the study. From the clinical safety parameter analysis, all the surgical gloves were safe to use and none of the users reported safety - related issues. The overall rating given by the user for product performance was excellent for all the products. All the users agreed that the product is meeting the product quality. The overall rating given by the user for product satisfaction is Excellent. None of the users have reported any undesirable events.*

Keywords: gloves, latex, allergy, healthcare workers

1. Introduction

Surgical gloves are vital components of infection control in the healthcare setting, serving as a barrier between healthcare professionals and potentially infectious materials. The selection of appropriate gloves is of utmost importance to ensure the safety of both patients and healthcare providers. Among the various types of surgical gloves available, latex gloves have been widely used for decades due to their excellent tactile sensitivity and elasticity. However, concerns regarding allergic reactions and the presence of powder particles have prompted the development of alternative materials, such as nitrile, which offer comparable performance without the risk of latex allergies.

This post - market clinical follow - up study aims to comprehensively evaluate and compare the safety and performance of three types of surgical gloves: Latex Surgical Gloves - Powdered, Latex Surgical Gloves - Powder Free, and Nitrile Surgical Gloves - Powder Free. The study aims to provide valuable insights into the clinical utility and advantages of each glove type, assisting healthcare professionals in making informed decisions while selecting gloves for surgical procedures.

Safety is of paramount importance in healthcare settings, and this study addresses concerns associated with latex gloves, including latex allergies and the potential adverse effects of glove powder. Latex allergies, ranging from mild skin irritation to severe anaphylactic reactions, have been

reported among healthcare workers and patients. Powdered gloves, commonly used to facilitate donning and doffing, have been associated with respiratory complications, wound contamination, and allergic responses. Consequently, the introduction of powder - free gloves, both latex, and nitrile, has aimed to mitigate these risks and improve overall safety.

Beyond safety considerations, the performance of surgical gloves is equally critical. Healthcare professionals rely on gloves to provide optimal tactile sensitivity, dexterity, and durability during surgical procedures. Maintaining a high level of performance ensures the accurate execution of delicate tasks and contributes to successful patient outcomes. Therefore, this study seeks to evaluate and compare the performance characteristics of powdered and powder - free latex gloves, as well as powder - free nitrile gloves, to determine their suitability for various surgical applications.

To accomplish these objectives, a comprehensive post - market clinical follow - up study has been conducted, involving rigorous evaluation and analysis of the selected glove types. The study includes an assessment of glove quality and barrier integrity. Additionally, it explores tactile sensitivity, grip control, and overall comfort experienced by healthcare professionals during glove usage. Furthermore, the study investigates the potential for glove - related adverse events, such as dermatological reactions, respiratory complications, and surgical site infections.

The findings from this study will contribute to evidence - based decision - making in selecting surgical gloves, taking

into account both safety and performance considerations. The results are anticipated to inform healthcare professionals, regulatory bodies, and glove manufacturers, facilitating the development of guidelines and standards that promote optimal patient and healthcare worker safety.

Primary Objective

The primary objective of this study was to confirm clinical performance and safety throughout the expected lifetime of the Surgical Gloves, the acceptability and to assess the Safety and Performance of these gloves with a post - market clinical study. The primary objective was also measuring if the product had met its intended use as claimed by Primus Gloves Private Limited.

Secondary Objective

The secondary objective was to determine any undesirable events under normal conditions of use and assess whether the risks outweigh the intended benefits of the device. This study was also designed to identify and analyze new emergent risks, known and unknown residual risks, and contraindications identified and formulated to address specific questions relating to the clinical safety or clinical performance of the device. The study focuses on identifying possible systematic misuse or off - label use of the device.

2. Materials and Methods

Study Design

The study was conducted as per guidelines of MDR 2017/745, ANNEX XIV, Part B PMCF - A Guide for Manufacturers and Notified Bodies, MDCG 2020 - 8 - Post - market clinical follow - up (PMCF) Report A guide for manufacturers and notified bodies and ISO 14155: 2020 - Clinical investigation of medical devices for human subjects - Good clinical practice.

This study was a prospective, non - comparative, single - center study. The study was reviewed and approved by the ACE Independent Ethics Committee of (DCGI Regd. No. ECR/141/Indt/KA/2013/RR - 19) to evaluate the safety and performance of Latex Surgical Gloves Powdered, Latex Surgical Gloves Powder - free, and Nitrile Surgical Gloves Powder Free.

Performance Considerations

The Performance characteristics listed below were assessed during the PMCF study:

- 1) Comfort of using the gloves
- 2) Easy removal of gloves
- 3) Ease of handling objects
- 4) Resistance to tear and wear
- 5) Grip
- 6) Flexibility
- 7) Fit of gloves
- 8) Thickness
- 9) Ability of gloves to prevent risk of contamination
- 10) Ability of gloves to prevent allergic reaction
- 11) Glove material

Side Effects/Adverse Events

This clinical study was designed to provide continued access to Surgical Gloves in eligible subjects who have no evidence of side effects/ adverse events such as:

- 1) Latex Allergy (Not applicable to Nitrile Surgical Gloves Powder Free)
- 2) Inflammation
- 3) Allergy
- 4) Pain
- 5) Rashes
- 6) Itching
- 7) Peeling of skin
- 8) Hypersensitivity type - I reaction (Not Applicable to Nitrile Surgical Gloves Powder Free)
- 9) Skin redness
- 10) Ulcerated skin

Study Population and Enrollment

The study population was selected by Simple Random Sample Stratification.

Materials

In this study, the gloves of the brand named Protac gloves manufactured by Primus Gloves Pvt. Ltd. were used for the PMCF study. Though the glove sizes are available in 6, 6.5, 7, 7.5, 8, 8.5, and 9 for Latex Surgical Gloves Powdered, Latex Surgical Gloves Powder Free and Nitrile Surgical Gloves Powder Free under the clinical study we considered only four glove sizes i. e., 6, 6.5, 7 and 7.5. Since the study was conducted in India, the glove size matched the Indian population are these four sizes only. Hence, we considered these sizes for the clinical study. Since there is no change in the material or properties of the gloves the clinical outcome from these four sizes of the gloves will be considered for other sizes also.

Latex Surgical Gloves Powdered:

The Latex Surgical Gloves – Powdered are made of natural rubber latex. The Latex Surgical Gloves – Powdered are sterile and disposable medical gloves. These are intended to use by healthcare professionals during medical procedures to help prevent cross - contamination between caregivers and patients. The Latex Surgical Gloves – Powdered are more precise sizing with better precision and complies as per the standards ASTM D3577 - 19 and EN 455. The Latex Surgical Gloves – Powdered are sterilized by Ethylene Oxide or Gamma Irradiation as per the customer's requirement.

Latex Surgical Gloves Powder Free:

The Latex Surgical Gloves – Powder Free are made of natural rubber latex. The Latex Surgical Gloves – Powder Free are sterile and disposable medical gloves. These are intended to use by healthcare professionals during medical procedures to help prevent cross - contamination between caregivers and patients. The Latex Surgical Gloves – Powder Free are more precise sizing with better precision and complies as per the standards ASTM D3577 - 19 and EN 455. The Latex Surgical Gloves – Powder Free are sterilized by Ethylene Oxide or Gamma Irradiation as per the customer's requirement.

Nitrile Surgical Gloves Powder Free:

The Nitrile Surgical Gloves – Powder Free are made of synthetic nitrile rubber latex. The Nitrile Surgical Gloves – Powder Free are sterile and disposable medical gloves. These are intended to use by healthcare professionals during medical procedures to help prevent cross - contamination between caregivers and patients. The Nitrile Surgical Gloves – Powder Free are more precise sizing with better precision and complies as per the standards ASTM D 3577 - 19 and EN 455. The Nitrile Surgical Gloves – Powder Free are sterilized by Ethylene Oxide or Gamma Irradiation as per the customer’s requirement.

Sample size

The total sample size was 756.

Duration of Study

The PMCF study was initiated on May 2022 and completed on June 2022. The duration of the study was two months.

Inclusion Criteria

- Informed consent from the PI on behalf of all the subjects
- Subjects in which Surgical Gloves are used during surgical procedures.

Exclusion Criteria

- Subjects without informed consent
- Subjects who are sensitive to natural latex rubber
- Subjects who are sensitive to synthetic latex (for nitrile gloves only)
- Subjects who are sensitive to powder content in Surgical Gloves Powdered.

3. Results

The clinical data were evaluated through Clinical data summary and Clinical Case Study reports for each subject on whom Latex Surgical Gloves Powdered, Latex Surgical

Gloves Powder Free, and Nitrile Surgical Gloves Powder Free were used. The study was initiated in May and got completed in June. The duration of the study was two months.

Overall, 756 subjects participated in the PMCF study, out of which Latex surgical gloves powdered were used by the users in 252 cases. Latex surgical gloves powder free were used by users on 252 cases. Nitrile Surgical Gloves Powder Free was used by users in 252 use cases.

Below is the gender distribution of subjects for whom the gloves were used during the surgery.

Table 1: Gender distribution of usage of the gloves

Product Name	Gender Distribution
Latex Surgical Gloves Powdered	Male: 132 (52%), Female: 120 (48%)
Latex Surgical Gloves Powder Free	Male: 112 (44%), Female: 140 (56%)
Nitrile Surgical Gloves Powder Free	Male: 129 (51%), Female: 123 (49%)

The age summary of the subjects from whom the data is collected is represented below.

Table 2: Age summary of patients in whom the gloves were used

Age Group	Latex Surgical Gloves Powdered	Latex Surgical Gloves Powder Free	Nitrile Surgical Gloves Powder Free
1 - 20 years	29 (12%)	30 (12%)	25 (10%)
21 - 40 years	72 (29%)	33 (13%)	80 (38%)
41 - 60 years	61 (24%)	65 (26%)	86 (34%)
61 - 80 years	79 (31%)	118 (47%)	61 (24%)
81 - 100 years	11 (4%)	6 (2%)	-----

The duration of the use of gloves is given below.

Table 3: Duration of glove usage

Product Name	Duration of using the gloves in surgeries/procedures	No: of subjects
Latex Surgical Gloves Powdered	Transient taken less than 60 minutes/1hr	60
	Medium - term use between 1 hour to 4 hours	164
	Long - term use of more than 4hrs	28
Latex Surgical Gloves Powder Free	Transient taken less than 60 minutes/1hr	60
	Medium - term use between 1 hour to 4 hours	173
	Long - term use of more than 4hrs	19
Nitrile Surgical Gloves Powder Free	Transient taken less than 60 minutes/1hr	115
	Medium - term use between 1 hour to 4 hours	99
	Long - term use of more than 4hrs	38

Below was the category of users who participated in the study

Table 4: Categories of healthcare workers who used the gloves

Type of users	Latex Surgical Gloves Powdered	Latex Surgical Gloves Powder Free	Nitrile Surgical Gloves Powder Free
Nurse	67	55	53
Doctor	185	197	199

Product Quality Analysis

The product quality analysis was evaluated by asking questions related to the quality parameters given below in the table. The users were asked to rate conditions based on the occurrence of these parameters.

Table 5: Product quality analysis of the gloves

Product Details	Latex Surgical Gloves Powdered		Latex Surgical Gloves Powder Free		Nitrile Surgical Gloves Powder Free	
	Yes	No	Yes	No	Yes	No
Secure hold on surgical instruments by glove	252 (100%)	0	252 (100%)	0	252 (100%)	0
Perfect glove size/fit	252 (100%)	0	252 (100%)	0	252 (100%)	0
Ability to follow IFU	252 (100%)	0	252 (100%)	0	252 (100%)	0
Color variation in gloves	0	252 (100%)	0	252 (100%)	0	252 (100%)
Powder removal before usage	252 (100%)	0	N/A	N/A	N/A	N/A

All the users agreed that the products were meeting the product quality; hence it was concluded that the product was meeting the quality as per the claim.

Clinical Safety and Efficacy

The Clinical Safety and efficacy of the Sterile Latex Surgical Gloves were evaluated by asking questions related to the clinical parameters given below

- 1) Any kind of hindrance in surgery while using the gloves
- 2) Increased adhesion to skin
- 3) Protection from blood stains or any fluids
- 4) Any holes or breakage in gloves
- 5) Any kind of sweating or any other discomfort while using the gloves
- 6) Any adverse effects in patients after the surgery
- 7) Prolong hospital stay due to the risk of post - surgical infection suspected from the usage of gloves
- 8) Any medications to treat the infection
- 9) Open a new pair of gloves due to any damage in the gloves
- 10) Protect your hands from blood or body fluids of the patient by the gloves

- 11) Resistance to puncture from other medical devices
- 12) Any high - risk reaction such anaphylaxis or severe symptoms

The users were asked to rate conditions based on the occurrence of these parameters in the subjects while they were undergoing the procedure. From the clinical safety parameter analysis, it was concluded that in all the cases users have given favorable responses to clinical safety parameters.

Summary on Performance

Clinical Performance

The clinical performance of the product was evaluated by asking the users to give satisfaction ratings in the case report form for the performance category. 756 samples were selected for the study. The rating was done on Likert Scale. Likert scale consisted of "Excellent=5", "Good=4", "Satisfactory=3", "Average=2" and "Unsatisfactory=1". All ratings correspond to each question added together to find the product performance in each attribute.

Table 6: Product performance of the gloves

	Latex Surgical Gloves Powdered	Latex Surgical Gloves Powder Free	Nitrile Surgical Gloves Powder Free
1. Easy removal of gloves	5	5	4.9
2. Ease of handling objects	4.9	4.9	4.9
3. Grip	4.9	5	5
4. Comfort of using the gloves	4.9	4.9	5
5. Flexibility	4.9	5	5
6. Resistance to tear and wear	5	5	5
7. Fit of gloves	5	5	5
8. Ability of gloves to prevent the risk of contamination	5	5	5
9. Glove material	4.9	5	4.9
10. Thickness	5	4.9	4.9
11. Ability of gloves to prevent an allergic reaction	5	5	5
Overall Rating	4.9	4.9	4.9

Latex Surgical Gloves Powdered:

The overall performance rating is "4.9", hence we can conclude that the product is showing "Excellent" performance on all parameters

Latex Surgical Gloves Powder Free:

The overall performance rating is "4.9", hence we can conclude that the product is showing "Excellent" performance on all parameters

Nitrile Surgical Gloves Powder Free:

The overall performance rating is "4.9", hence we can conclude that the product is showing "Excellent" performance on all parameters.

None of the users reported any adverse events/side effects during the study. There were no new risks identified during the study.

The product user rating given by the user is 5, which is Excellent as per the definition. Hence this proves that the users were happy with the product and it meets its purpose.

4. Discussion

Over time, medical gloves have undergone significant evolution to meet the specific requirements of the medical field. The increased utilization of latex gloves began in the 1980s when awareness of HIV/AIDS prompted a surge in

their usage. The primary purpose of gloves in healthcare is to provide an effective barrier that safeguards both healthcare professionals and patients from infections. It is essential that gloves used by healthcare workers are single-use for each patient interaction and treatment while avoiding prolonged and indiscriminate use to minimize the risk of sensitization.¹⁻³

Medical gloves are crucial in various situations such as invasive procedures and contact with non-intact skin, mucous membranes, or sterile sites. Therefore, it is imperative to ensure minimal leakage, even when gloves appear undamaged. To guarantee consistent performance across different materials, various standards have been developed to assess glove adequacy. Key considerations for gloves include ease of donning, comfort during wear, and providing durable protection.^{4,5}

Natural rubber latex (NRL) is predominantly obtained from the *Hevea brasiliensis* tree, and it contains the rubber polymer, cis-polyisoprene, as well as various proteins. While chemicals are used during glove manufacturing, a significant proportion of these chemicals are leached out in subsequent stages of production, along with most water-soluble proteins found in NRL.^{3,6}

The initial medical gloves, introduced in the 1880s, were thick and reusable, made from natural rubber. Sterilization was achieved through boiling, and powder was added to prevent sticking and ease donning. In the 1960s, disposable gloves made from NRL were produced, which were naturally sticky, leading to the use of powder or lubricants. However, certain powders, such as Lycopodium fragments and talcum powder, were later discovered to cause adverse reactions. Modified cornstarch powder was widely used until its adverse effects were uncovered, necessitating a shift towards powder-free gloves.⁷⁻⁹

Recent efforts have focused on reducing the levels of NRL protein allergens, chemical residuals, and endotoxins in gloves and powder. These reductions aim to minimize adverse reactions associated with gloves, including foreign body reactions, Type IV hypersensitivity, Type I reactions to NRL protein allergens, and endotoxin-related consequences.⁷⁻¹⁰

A study by Palosuo et al suggests a reevaluation of latex medical gloves due to the increasing prevalence of latex allergies. The authors emphasize the need for a standardized approach to assess the allergenicity of latex gloves and advocate for the development of effective latex alternatives that offer equivalent protection against infectious agents. They propose a balanced approach of using a mix of latex and synthetic gloves, with synthetic gloves preferred for known latex-allergic individuals.⁶ In this study, no adverse events were noticed with the usage of the latex gloves.

Powdered surgical gloves, previously used to ease donning, have been associated with health hazards. They have been linked to foreign-body granulomas, adhesions causing small-bowel obstruction, aeroallergens, Type I hypersensitivity to latex proteins, interference with HIV antibody tests, and polymerase chain reactions. Alternatives

to powdered gloves, such as polymer-coated or low-latex protein gloves, are now available.^{7,8} No adverse events were reported in this study with the usage of powdered gloves.

Studies examining glove durability indicate that NRL gloves provide lower rates of perforation and viral leakage compared to vinyl gloves. Post-usage examinations of surgical gloves have shown higher defect rates in non-latex gloves compared to latex gloves. Additionally, latex gloves have demonstrated significantly lower perforation rates compared to latex-free gloves during high-risk surgical procedures.⁴ All the gloves used in the present study were durable and no perforations were reported.

Nitrile gloves are comparable to latex gloves in terms of barrier effectiveness against blood-borne pathogens, puncture resistance, and durability. However, they may have lower tensile strength and higher stiffness compared to latex. Nitrile gloves tend to be designed with a looser fit due to their higher permanent set after stretching, potentially affecting tactile sensation.¹¹⁻¹³ The users reported no adverse events and were comfortable with the usage of nitrile gloves in this study.

A study by Basak et al compared the perforation resistance, user satisfaction, and manual dexterity of latex, nitrile, and neoprene surgical gloves. Nitrile gloves exhibited the highest perforation resistance, user satisfaction, and manual dexterity, followed by latex and neoprene gloves. These findings provide valuable insights for healthcare professionals and organizations in selecting the most suitable surgical gloves.¹⁴ In the current study, no user-reported events like perforation were reported. All the gloves were of adequate fit and did not hinder the user's hand movements.

A study focused on the rate of glove punctures among scrub nurses during surgeries. It revealed higher puncture rates in single and double gloves compared to powder and latex-free gloves. Longer procedures increased the risk of puncture, with all punctures occurring in the outer gloves of double-gloving techniques. Scrub nurses reported less discomfort with powder and latex-free gloves compared to latex and powdered gloves. Further research is needed to determine the most effective gloves for infection prevention while considering tactile sensation and minimizing puncture rates.^{11,14}

In summary, medical gloves have evolved to meet the specific demands of the medical field. The use of latex gloves has raised concerns due to increasing latex allergies, leading to the development of low-allergen, low-protein, and powder-free latex gloves as a potential solution. Alternatives to powdered gloves, such as polymer-coated or low-latex protein gloves, are now available. Nitrile gloves have shown comparable performance to latex gloves in various aspects. Factors like barrier effectiveness, puncture resistance, user satisfaction, and manual dexterity play a significant role in determining the suitability of different glove materials for specific healthcare applications.^{3,10,12-14} Healthcare workers who are at risk of latex allergy should avoid using powdered examination gloves. Instead,

they should use non - powdered gloves or gloves made from synthetic materials. Patients who are allergic to latex should also avoid contact with powdered gloves.¹⁵

5. Conclusion

The study included 756 subjects of which Latex Surgical Gloves Powdered and Powder Free and Nitrile Surgical Gloves Powder free were used. This prospective study has proven the safety and performance of using the product.

The Surgical Gloves from Primus Gloves Private Limited has reached all the safety and performance requirements with respect to the intended use of the Device from the Post Market Clinical Follow up study. From the study the performance of all the product is Excellent and it is safe to use. There were no new risks identified from the study for the products hence there is no addition to the residual risks which we have already identified in the Risk Management Report and that is been mitigated and are acceptable when weighed against the benefits to the patient. None of the users reported any infection under normal condition of use and there were no serious adverse events or adverse events reported. None of the users had reported any contraindication, misuse or off label use of the device.

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