International Journal of Research and Review
Vol. 10; Issue: 3; March 2023
Website: www.ijrrjournal.com
Original Research Article *E-ISSN: 2349-9788; P-ISSN: 2454-2237*

Revisiting Latex Gloves in Healthcare - A Post-Market Clinical Study

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DOI: https://doi.org/10.52403/ijrr.20230342

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. The purpose of the study was to evaluate the safety and performance of Sterile Latex Surgical Gloves- Powdered and Powder Free, Sterile Latex Gynaecological Gloves- Powdered and Powder Free. Overall, 976 subjects participated in the study, out of which sterile latex surgical gloves were used by the users in 288 cases. Sterile latex surgical gloves powder free was used by users in 291 cases. Sterile Latex Gynaecological Gloves Powdered were used by users in 201 cases and Sterile Latex Gynaecological Gloves Powder Free was used in196 cases. From the clinical safety parameter analysis, sterile latex 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

INTRODUCTION

Latex gloves have been widely used in the healthcare industry for decades due to their versatility, affordability, and excellent barrier protection. They are essential for preventing the transmission of pathogens and are used in a variety of settings, including hospitals, clinics, and laboratories. Despite their widespread use, there is limited information available on the clinical performance of latex gloves. In this study, we aim to evaluate the clinical use of latex gloves in real-world settings and gather data on their performance and usability. The results of this study will provide valuable insights into the practical aspects of using latex gloves and will inform best practices for their use in clinical settings. The findings of this study will be of interest to healthcare professionals, researchers, and manufacturers of latex gloves, and will contribute to the continued development of this important personal protective equipment.

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. Surgical gloves have more precise sizing with better

precision and sensitivity and are made to a higher standard. The main difference between surgical gloves and medical examination gloves are:

1. Manufacturers of surgical gloves are required to meet a higher level of quality standards
2. Surgical gloves are sterile and individually packaged in pairs
3. Surgical gloves have a more precise range of sizing than medical examination gloves.

Elements other than the glove material that determine the level of barrier protection include the length of time the gloves are worn, chemicals coming into contact with the glove, and handling of equipment that may stress the glove material and the fit of the glove; poorly fitting gloves offer less protection.

Sterile Latex Surgical gloves – Powdered is made from natural rubber latex which provides excellent tactile sensitivity and comfort. Latex materials are known to have very high elasticity meaning the gloves can stretch well to allow easy donning of the gloves. Surgical gloves are often added with cornstarch powder to reduce friction. They are called powdered surgical gloves. The powder acts as a lubricant and facilitates the easy wearing of gloves. It also absorbs any sweating done, inside the gloves. In the latex gloves, the powder absorbs the latex particles and behaves as a carrier, which predisposes to allergy. And this type of disposable glove is also more resistant to tears and rips than powder-free options.

Sterile Latex Surgical gloves – Powder Free is made of natural rubber and chemical additives. They have a micro-textured surface and are cream or natural in color. The gloves are made powder free by polymer coating with a unique blend of polymer to provide excellent dry and damp hand-donning capabilities. The powder-free gloves can be used for avoiding any risk due to powder in critical surgeries as an added precaution.

Sterile Latex Gynaecological Gloves- Powdered is made from natural rubber latex which provides excellent tactile sensitivity and comfort. Latex materials are known to have very high elasticity meaning the gloves can stretch well to allow easy donning of the gloves. They are anatomically shaped and highly flexible, hence minimizing user fatigue. The extra length gives excellent barrier protection from fluid contamination. Uncompromised quality control ensures that each glove provides maximum protection against cross contaminations while providing superior comfort.

Sterile Latex Gynaecological Gloves – Powder Free is suggested for surgical application as the powder on gloves can enter the patient's body during surgery, which may trigger an inflammatory response by the immune system, leading to the formation of fibrous bands and post-operative adhesions. Sterile latex gynaecological gloves help doctors avoid direct contact with blood and mucous membranes that occurs in 25% of vaginal deliveries and 35% of caesarean sections. These gloves also protect doctors from significant blood and amniotic fluid contamination. These gloves which cover a substantial portion of the forearm, up to just below the elbow, can legitimately be called "long gloves". They are highly flexible and comfortable, hence minimizing user fatigue.

The purpose of the study was to evaluate the safety and performance of Sterile Latex Surgical Gloves- Powdered and Powder Free, Sterile Latex Gynaecological Gloves- Powdered and Powder Free.

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.

Primary Objective

To demonstrate clinical safety of the Sterile Latex Surgical Gloves- Powdered and Powder Free, Sterile Latex Gynaecological Gloves- Powdered and Powder Free and to observe any undesirable events like infection under normal conditions of use.

Secondary Objective

To demonstrate the performance of Sterile Latex Surgical Gloves- Powdered and Powder Free, Sterile Latex Gynaecological Gloves- Powdered and Powder Free.

MATERIALS & 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 was a prospective non-randomized open-label study that evaluated the safety and performance of Sterile Latex Surgical Gloves- Powdered and Powder Free and Sterile Latex Gynaecological Gloves- Powdered and Powder Free during single operative or gynaecological procedure. During the study, the healthcare professional used Sterile Latex Surgical Gloves- Powdered and Powder Free, and Sterile Latex Gynaecological Gloves- Powdered and Powder Free to evaluate their safety and performance during the surgery. Post-surgery occurrence of infection was also documented. The glove was visually checked by the user for any leakage and perforations and contamination to the hand by blood or body fluid was recorded in the case report form designed for the study.

During this prospective study doctors and nurses used these gloves for various surgical, invasive, and non-invasive procedures. In this study, subjects are the patients who had undergone the procedures using the Sterile Latex Surgical Gloves - Powdered and Powder Free and Sterile Latex Gynaecological Gloves Powdered and Powder Free.

The study was conducted in a tertiary care hospital. The data was collected from the end users who have used Sterile Latex Surgical Gloves (Powdered and Powder Free) for the following indication:

1. To prevent contamination of the patient during invasive procedures
2. To prevent surgical site infections and reduce the risk of exposure to blood and body fluid pathogens for the health care worker.

The study was reviewed by the ACE Independent Ethics Committee of (DCGI Regd. No. ECR/141/Indt/KA/2013/RR-19) and the study was commenced after the approval from the committee.

Safety assessments were considered for all the subjects participating in the study. Clinical activity was assessed using the local standard of care and the appropriate response criteria as determined by the locally available Surgeons/Operation Theatre Personnel /Healthcare providers

Performance Considerations

Performance characteristics listed below were assessed during the study for sterile latex surgical gloves:

1. Ease of removal of gloves
2. Ease of handling objects
3. Grip
4. Comfort of using the gloves
5. Flexibility and sensitivity
6. Resistance to tear and wear
7. Fit of gloves
8. Ability of gloves to prevent the risk of contamination
9. Glove material
10. Thickness
11. Ability of gloves to prevent allergic reactions
12. Side Effects/Adverse Events
13. This clinical study was designed to document any adverse events such as:
14. Allergy
15. Itching
16. Rashes

17. Inflammation
18. Pain
19. Surgical site infection
20. Latex Allergy
21. Skin redness
22. Ulcerated skin
23. Peeling of skin
24. Hypersensitivity type-I reaction

Study Population and Enrollment

The study population was selected by Simple Random Sample Stratification.

Materials

In this study two brands viz., Medismart and Medismart+ manufactured by St Mary's Rubbers Pvt Ltd, Kerala, India was used in sizes 5½, 6, 6½, 7, 7½, 8, 8½, and 9. The total sample size was 976.

Duration of Study

The entire duration of the study was 6 months. The study was initiated on November 2021 and was completed on April 2022.

Inclusion Criteria

1. Subjects to be included in the study must meet the following eligibility criteria:
2. Informed consent from the subject
3. Subjects on whom Sterile Latex Surgical Gloves Powdered and Powder Free were used for surgical and gynecological procedures.

Exclusion Criteria

1. Subjects without informed consent
2. Subjects who are sensitive to latex
3. Subjects who are sensitive to powder content in Sterile Latex Surgical Gloves Powdered and Sterile Latex Gynaecological Gloves Powdered.

RESULT

Overall, 976 subjects participated in the PMCF study, out of which sterile latex surgical gloves were used by the users in 288 cases. Sterile latex surgical gloves powder free was used by users in291 cases. Sterile Latex Gynaecological Gloves Powdered was used by users in 201 cases and Sterile Latex Gynaecological Gloves Powder Free was used by users in 196 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
Sterile Latex Surgical Gloves Powdered	182 (63%) Male 106 (37%) Female
Sterile Latex Surgical Gloves Powder Free	184 (63 %) Male 107 (37 %) Female
Sterile Latex Gynaecological Gloves Powdered	201 (100 %) Female
Sterile Latex Gynaecological Gloves Powder Free	196 (100 %) Female

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	Sterile Latex Surgical Gloves Powdered	Sterile Latex Surgical Gloves Powder Free	Sterile Latex Gynaecological Gloves Powdered	Sterile Latex Gynaecological Gloves Powder Free
1-20 years	18(6%)	18(6%)	22(11%)	22(11%)
21-40 years	76(26%)	77(26%)	106(53)%	104(53%)
41-60 years	88(31%)	90(31%)	49(24)%	48(25%)
61-80 years	85(30%)	85(29%)	24(12)%	22(11%)
81-100 years	21(7%)	21(7%)	0	0

The different sizes of gloves used in the study are given below.

Table 3: Distribution of various sizes of gloves used in the study

Glove size	Sterile Latex Surgical Gloves Powdered	Sterile Latex Surgical Gloves Powder Free	Sterile Latex Gynaecological Gloves Powdered	Sterile Latex Gynaecological Gloves Powder Free
5½	44	44	Nil	Nil
6	45	45	Nil	Nil
6½	50	50	44	44
7	46	46	Nil	Nil
7½	57	57	38	38
8	46	49	Nil	Nil
8½	00	00	119	114
9	00	00	Nil	Nil

The duration of the use of gloves is given below.

Table 4: Duration of glove usage

Product Name	Duration of using the gloves in surgeries/procedures	No: of subjects
Sterile Latex Surgical Gloves Powdered	Transient taken less than 60 minutes/1hr	37
	Medium-term use between 1 hour to 4 hours	221
	Long-term use of more than 4hrs	30
Sterile Latex Surgical Gloves Powder Free	Transient taken less than 60 minutes/1hr	38
	Medium-term use between 1 hour to 4 hours	223
	Long-term use of more than 4hrs	30
Sterile Latex Gynaecological Gloves Powdered	Transient taken less than 60 minutes/1hr	125
	Medium-term use between 1 hour to 4 hours	76
	Long-term use of more than 4hrs	0
Sterile Latex Gynaecological Gloves Powder Free	Transient taken less than 60 minutes/1hr	123
	Medium-term use between 1 hour to 4 hours	73
	Long-term use of more than 4hrs	0

Below was the category of users who participated in the study

Table 5: Categories of healthcare workers who used the gloves

Type of users	Sterile Latex Surgical Gloves Powdered	Sterile Latex Surgical Gloves Powder Free	Sterile Latex Gynaecological Gloves Powdered	Sterile Latex Gynaecological Gloves Powder Free
Nurse	139	139	57	57
Doctor	149	152	144	139

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 6: Product quality analysis of the gloves

Product Details	Sterile Latex Surgical Gloves Powdered (288 cases)		Sterile Latex Surgical Gloves Powder Free (291 cases)		Sterile Latex Gynaecological Gloves Powdered (201 cases)		Sterile Latex Gynaecological Gloves Powder Free (196 cases)	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
Secure hold on surgical instruments by glove	288(100%)	0	291(100%)	0	201(100%)	0	196(100%)	0
Perfect glove size/fit	288(100%)	0	291(100%)	0	201(100%)	0	196(100%)	0
Ability to follow IFU	288(100%)	0	291(100%)	0	201(100%)	0	196(100%)	0
Color variation in gloves	0	288(100%)	0	291(100%)	0	201(100%)	0	196(100%)
Powder removal before usage	0	288(100%)	N/A	N/A	N/A	N/A	N/A	N/A

All the users agreed that the product was 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 in tables 7 and 8. The users were asked to rate

conditions based on the occurrence of these parameters in the subjects while they were undergoing the procedure.

An analysis of the safety parameters of each product is given below.

Table 7: Clinical Safety and Efficacy of Sterile Latex Surgical Gloves Powdered and Powder Free

Safety Parameter	Sterile Latex Surgical Gloves Powdered (288 cases)		Sterile Latex Surgical Gloves Powder Free (291 cases)	
	YES	No	YES	No
Any adverse effects in patients after the surgery	0	288(100%)	0	291(100%)
Any kind of sweating or any other discomfort while using the gloves	0	288(100%)	0	291(100%)
Protection from blood stains or any fluids	288(100%)	0	291 (100%)	0
Increased adhesion to skin	0	288(100%)	N/A	N/A
Prolong hospital stay due to the risk of post-surgical infection suspected from the usage of gloves	0	288(100%)	0	291 Nil (100%)
Any medications to treat the infection	0	288 Nil (100%)	0	291 (100%)
Any holes or breakage in gloves	0	288(100%)	0	291 (100%)
Any kind of hindrance in surgery while using the gloves	0	288(100%)	N/A	N/A
Open a new pair of gloves due to any damage in the gloves	0	288(100%)	0	291 (100%)
Protect your hands from the blood or body fluids of the patient with the gloves	288(100%)	0	291 (100%)	0
Resistance to punctures from other medical devices	288(100%)	0	291 (100%)	0
Any high-risk reaction such as anaphylaxis or severe symptoms	0	288(100%)	0	291(100%)

Table 8: Clinical Safety and Efficacy of Sterile Latex Gynaecological Gloves Powdered Powder Free

Safety Parameter	Sterile Latex Gynaecological Gloves Powdered (201 cases)		Sterile Latex Gynaecological Gloves Powder Free (196 cases)	
	YES	NO	YES	NO
The glove size was appropriate for your hand size	201(100%)	0	196(100%)	0
Any adverse effects in patients after the surgery	0	201(100%)	0	196(100%)
Any kind of sweating or any other discomfort while using the gloves	0	201(100%)	0	196(100%)
Gloves protect you from blood stains or any fluids	201(100%)	0	196(100%)	0
Prolong the hospital stay due to the risk of post-surgical infection suspected from the usage of gloves	0	201(100%)	0	196(100%)
Any medications to treat the infection	NIL	NIL	NIL	NIL
Any holes or breakage in gloves	0	201(100%)	0	196(100%)
Any kind of hindrance in the procedure while using the gloves	0	201(100%)	0	196(100%)
Provide enough grip during Gynecological procedures	201(100%)	0	196(100%)	0
Prevent contamination in gynaec surgeries/ procedures	201(100%)	0	196(100%)	0

From the clinical safety parameter analysis, it was concluded that in all the use cases users have given favorable responses to clinical safety parameters.

All the users had agreed that the Sterile Latex Gloves Powdered and Powder Free had met the intended use.

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. 976 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 9: Product performance of the gloves

Product Performance	Product Performance Rating given by the user			
	Sterile Latex Surgical Gloves Powdered	Sterile Latex Surgical Gloves Powder Free	Sterile Latex Gynaecological Gloves Powdered	Sterile Latex Gynaecological Gloves Powder Free
1.Easy removal of gloves	4.98	4.98	5	5
2.Ease of handling objects	4.98	4.98	N/A	5
3. Grip	4.98	4.98	5	5
4. Comfort of using the gloves	4.99	5	5	5

Table 9 To Be continued…				
5. Flexibility	4.96	4.98	5	5
6. Resistance to tear and wear	5	5	5	5
7. Fit of gloves	5	5	5	5
8. Ability of gloves to prevent the risk of contamination	5	5	5	5
9. Glove material	5	5	5	5
10. Thickness	4.98	4.98	5	5
11. Ability of gloves to prevent an allergic reaction	5	5	5	5
Overall Rating	4.98	4.9	5	5

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

The overall product satisfaction by the user/investigator is expressed in the case report form. The product user rating given by the user is 10, which is Excellent as per the definition.

Follow-Up Study Summary

Safety Parameters:

The users were asked to rate conditions based on the occurrence of these parameters in the subjects when they came for the follow-up visit.

Table 10: Follow-Up Study Summary

Safety Parameters	Sterile Latex Surgical Gloves Powdered (288 use cases)		Sterile Latex Surgical Gloves Powder Free (291 use cases)		Sterile Latex Gynaecological Gloves Powdered (201 use cases)		Sterile Latex Gynaecological Gloves Powder Free (196 use cases)	
	YES	NO	YES	NO	YES	NO	YES	NO
Any kind of adverse effects or allergic reaction after surgery within 72 hrs of using the gloves	0	288(100%)	0	291 (100%)	0	201 (100%)	0	196 (100%)
Any discomfort like an allergic reaction or inflammation from the gloves after the surgery	0	288(100%)	0	291 (100%)	0	201 (100%)	0	196 (100%)

None of the users had reported any kind of adverse effects, allergic reactions, or inflammation after surgery within 72 hours of using the gloves.

DISCUSSION

Medical gloves have evolved to meet the needs of the medical field. The dramatic increase in the use of latex gloves began in the 1980s following a greater awareness of HIV/ AIDS. The primary function of gloves is to provide a competent barrier to protect against infections for both healthcare professionals and patients. Gloves used by healthcare workers need to be single use for each patient contact and treatment, although it is recommended that prolonged and indiscriminate use should be avoided to minimize the risk of sensitization.

They are required in various situations such as invasive procedures and contact with non-intact skin, mucous membranes, or sterile sites. As such, leakage must be minimal, even when apparently undamaged, and various standards have been developed so that all gloves perform adequately regardless of material. They should be easy to put on, comfortable to wear, and provide adequate, durable protection.

Many plants produce liquid latex, but the natural material, natural rubber latex (NRL), used in rubber manufacture is almost exclusively obtained from the Hevea brasiliensis tree. It contains the rubber polymer, cis-poly-isoprene, as well as varying amounts of a large number of different proteins. Various chemicals, such as accelerators, activators, anti-oxidants, and vulcanizing agents, are used in the

manufacture of medical gloves but a large proportion of these chemicals are then leached out in the further stages of production, through processes such as 'wet-gel leaching'. These leaching processes also remove the majority of the water-soluble proteins found in NRL.[1,2]

The first medical gloves were introduced in the 1880s and were made of thick, reusable natural rubber. These gloves were sterilized by boiling and were donned over wet hands. With the introduction of steam sterilization or autoclaving, the powder was sprinkled into the gloves to prevent them from sticking to themselves and to make them easier to don. In the 1960s, the production of pre-sterilized, disposable gloves made from natural rubber latex (NRL) began. These gloves are naturally sticky, so a powder or lubricant was used to prevent them from sticking to each other, to the mold from which they were made, or to the hands.[3]

The early powders used for this purpose were made from Lycopodium fragments, but it was later discovered that this material could cause severe granulomas and adhesions. Talcum powder was introduced as a replacement, but it too was later implicated in adverse reactions. Another type of powder, modified cornstarch, was introduced and used widely in the medical field until its adverse effects were discovered, including adhesions, infertility, central nervous system complications, and an increased risk of infection.[3]

In recent years, the focus has been on reducing the levels of NRL protein allergens, chemical residuals, and endotoxin found on gloves and in the glove powder. This is to reduce the incidence of adverse reactions associated with the powder, including foreign body reactions, Type IV hypersensitivity, Type I reactions to NRL protein allergens, and endotoxin-related consequences. Reducing these substances will help reduce the amount absorbed by the powder and thus reduce the incidence of adverse reactions.[3]

The study by Palosuo et alcalls for a reappraisal of latex medical gloves. They believe that the use of latex gloves should be reconsidered in light of the increasing prevalence of latex allergies. The authors highlight the fact that there is wide variability in the allergenicity of latex gloves and that there is a need for a standardized approach to determining the allergenicity of these gloves. They also call for the development of more effective alternatives to latex gloves that provide equivalent protection against the transmission of infectious agents.[1]

The study argues that Natural Rubber Latex (NRL) remains a suitable material for medical gloves despite the reduced incidence of allergic reactions. The authors suggest that the benefits of NRL gloves, such as high barrier performance, good comfort, competitive pricing, and environmental sustainability, can be retained by purchasing low-allergen, low-protein, and powder-free gloves. This can help reduce the risk of type I and type IV sensitization and allergic reactions. The authors suggest that a mix of latex and synthetic gloves is a sensible balance, with synthetic gloves being used for known latex-allergic patients and staff.[1]

Powdered surgical gloves were once used to make it easier to put them and have been linked to health hazards. They can cause foreign-body granulomas and lead to the formation of adhesions, which are common causes of small-bowel obstruction.[4] The use of powdered gloves has also been linked to aeroallergens, type I hypersensitivity to latex proteins, false-negative HIV-antibody tests, and interference with polymerase chain reactions.[3,5]

Healthcare workers who are sensitive to latex should be identified and advised to avoid all latex-containing products. Alternatives to powdered gloves, such as gloves coated with a polymer or those with low latex-protein concentrations, are now available.[1,2,6–9]

However, it is up to users to stop using powdered gloves and gloves that are high in

extractable latex proteins, and sensitized individuals will need to avoid latex altogether.

The study of natural rubber latex allergens in gloves used by healthcare workers in Singapore aimed to determine the levels of latex allergens in gloves used by healthcare workers and to assess the risk of latex sensitization and allergic reactions among healthcare workers. The results showed that the levels of latex allergens in the gloves were relatively low, but still posed a risk for healthcare workers who are highly exposed to latex gloves. The authors concluded that more research is needed to determine the optimal levels of latex allergens in gloves to minimize the risk of latex sensitization and allergic reactions among healthcare workers. The current study showed no such adverse events in the users of these gloves.[10]

A study to evaluate the abrasion resistance of medical glove materials was conducted. The researchers aimed to determine the durability of gloves made from different materials, as abrasion resistance is a key factor in the selection of gloves for medical use. To test the abrasion resistance of the materials, the researchers subjected samples of gloves made from various materials to abrasion testing using a modified Taber abrasion tester. The results of the study showed that gloves made from nitrile and neoprene had the highest level of abrasion resistance, while gloves made from latex had the lowest level of abrasion resistance. The researchers also found that the thickness of the gloves played a significant role in determining the level of abrasion resistance, with thicker gloves providing better protection against abrasion.[11]

In conclusion, the study found that the abrasion resistance of medical gloves is dependent on both the material and the thickness of the gloves. The researchers recommended that when selecting gloves for medical use, healthcare providers should consider the level of abrasion resistance of the gloves, as well as other factors such as fit, comfort, and protection against infections.[11] None of the users in the current study faced any issues related to the product quality including tears while using the gloves.

A range of glove materials was tested for barrier effectiveness against blood-borne pathogens, simulated clinical use, puncture resistance, and durability, and in all these tests vinyl and copolymer gloves gave a worse performance than latex gloves. However, nitrile gloves performed comparably with latex.[12]

Comparing the level of dexterity offered by latex and nitrile gloves there was a statistically significant 8.6% increase in fine finger dexterity provided by latex compared with nitrile laboratory gloves but no difference in gross dexterity between the glove types. There was no significant relationship between glove dexterity and age or gender. The selection of glove size was influenced by the digit length of participants. Moreover, those with longer, thinner fingers appeared to have an advantage when using nitrile gloves. The level of dexterity provided by latex and nitrile gloves for tasks on a gross dexterity level is comparable.[13]

The durability of barrier protection has been examined in several studies and it has been shown that NRL gloves provide lower rates of perforation and lower viral leakage rates than vinyl gloves.[11,12]

In a study that examined gloves after manipulation to simulate in-use conditions, the failure rate was 0–4% for NRL, 1–3% for nitrile, and 12–61% for vinyl gloves, indicating better barrier protection by NRL and nitrile gloves, compared to vinyl.

Barrier integrity following an abrasion test demonstrated that NRL gloves were better than vinyl, although not as good as either nitrile or neoprene.

A study in the USA in 2004 performed a post-usage examination and testing of surgeons' gloves after routine surgical procedures. The results revealed higher after-use defects for non-latex compared with latex gloves.[14]

A recent study comparing synthetic polyisoprene and NRL gloves during heavy

orthopedic surgery with a high risk of perforations revealed a significantly higher perforation rate in latex-free gloves (80.0%) compared with NRL gloves (34.4%).[6]

According to the Scientific Committee on Medicinal Products and Medical Devices of the European Commission, nitrile gloves are usually of lower tensile strength than latex gloves, but their elastic modulus, or stiffness, is somewhat higher. In addition, nitrile has a higher permanent set than latex, meaning that once stretched it does not fully recover. Thus, nitrile gloves tend to be designed to fit more loosely than latex, and the combination of these properties may affect the users' tactile sensation and delicacy of touch. This has been confirmed by a study where participants noted that nitrile gloves that fitted their fingers were too narrow for their hands and gloves that fitted their hands were too large for their fingers.[1,12,13]

The study by Basak et al aimed to compare the perforation, satisfaction, and manual dexterity of three types of surgical gloves: latex, nitrile, and neoprene. The study involved measuring the perforation resistance of the gloves through an inflation test, evaluating user satisfaction through a questionnaire, and assessing manual dexterity through the Finger Tap Test. The results showed that nitrile gloves had the highest perforation resistance, followed by latex and neoprene gloves. Regarding user satisfaction, nitrile gloves received the highest score, followed by latex and neoprene gloves. In terms of manual dexterity, nitrile gloves performed the best, followed by latex and neoprene gloves. The study concluded that nitrile gloves had the best overall performance in terms of perforation resistance, user satisfaction, and manual dexterity, followed by latex and neoprene gloves. The findings of this study provide valuable information for healthcare professionals and organizations in choosing the most appropriate type of surgical gloves for their needs.[15]

The study examines the rate of glove punctures among scrub nurses during surgeries. The results show that 19% of single gloves and 18.1% of double gloves were punctured, while only 4.8% of powder and latex-free gloves were punctured. The study found that the risk of puncture increased significantly in procedures that lasted longer than 2 hours. In addition, all punctures in double gloves occurred in the outer gloves, while no punctures were detected in the inner gloves. The study also found that scrub nurses reported less discomfort with powder and latex-free gloves compared to latex and powdered gloves. The findings suggest that scrub nurses are at least as much at risk as surgeons in terms of exposure to infectious pathogens. Further studies are needed to investigate the best type of surgical gloves to prevent infection and disease transmission while maintaining different tactile sensations and minimizing puncture rates. [15]

CONCLUSION

The Sterile Latex Surgical Gloves Powdered and Powder Free from St. Marys Rubbers Private Limited have reached all the safety and performance requirements concerning the intended use of the Device from the Post Market Clinical Follow-up study. From the study, it was noted that the performance of all four products was excellent and it is safe to use. There were no new risks identified from the study for the products hence there was no addition to the residual risks. None of the users reported any infection under normal conditions of use and there were no serious adverse events or adverse events reported.

Declaration by Authors

Acknowledgement: None
Source of Funding: None
Conflict of Interest: The authors declare no conflict of interest.

REFERENCES

1. Palosuo T, Antoniadou I, Gottrup F, Phillips P. Latex medical gloves: time for a

reappraisal. *Int Arch Allergy Immunol* 2011; 156: 234–246.
2. Yip E, Cacioli P. The manufacture of gloves from natural rubber latex. *J Allergy Clin Immunol* 2002; 110: S3-14.
3. Truscott W. Glove powder reduction and alternative approaches. *Methods San Diego Calif* 2002; 27: 69–76.
4. Baid R, Agarwal R. Powdered gloves: Time to bid adieu. *J Postgrad Med* 2017; 63: 206.
5. Poole C. Hazards of powdered surgical gloves. *The Lancet* 1997; 350: 973–974.
6. Aldlyami E, Kulkarni A, Reed MR, Muller SD, Partington PF. Latex-free gloves: safer for whom? *J Arthroplasty* 2010; 25: 27–30.
7. Brown RH, Taenkhum K, Buckley TJ, Hamilton RG. Different latex aeroallergen size distributions between powdered surgical and examination gloves: significance for environmental avoidance. *J Allergy Clin Immunol* 2004; 114: 358–363.
8. Crippa M, Balbiani L, Baruffini A, Belleri L, Draicchio F, Feltrin G *et al.* [Consensus Document. Update on latex exposure and use of gloves in Italian health care settings]. *Med Lav* 2008; 99: 387–399.
9. Potter PC. Latex allergy: 'plight, rights and fights'. *South Afr Med J Suid-Afr Tydskr Vir Geneeskd* 2013; 103: 369–370.
10. Koh D, Ng V, Leow Y-H, Goh CL. A study of natural rubber latex allergens in gloves used by healthcare workers in Singapore. *Br J Dermatol* 2005; 153: 954–959.
11. Walsh DL, Schwerin MR, Kisielewski RW, Kotz RM, Chaput MP, Varney GW, *et al.* Abrasion resistance of medical glove materials. *J Biomed Mater Res B Appl Biomater* 2004; 68: 81–87.
12. Rego A, Roley L. In-use barrier integrity of gloves: latex and nitrile superior to vinyl. *Am J Infect Control* 1999; 27: 405–410.
13. Sawyer J, Bennett A. Comparing the level of dexterity offered by latex and nitrile SafeSkin gloves. *Ann Occup Hyg* 2006; 50: 289–296.
14. Korniewicz DM, Garzon L, Seltzer J, Feinleib M. Failure rates in nonlatex surgical gloves. *Am J Infect Control* 2004; 32: 268–273.
15. Basak T, Sahin G, Demirtas A. Comparison of surgical gloves: perforation, satisfaction and manual dexterity. *Int J Occup Saf Ergon* 2022; 28: 1160–1166.

How to cite this article: Murali Mohan S, Niranjan P, Ramya K S et.al. Revisiting latex gloves in healthcare - a post-market clinical study. *International Journal of Research and Review*. 2023; 10(3): 359-369.
DOI: *https://doi.org/10.52403/ijrr.20230342*

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