



RESEARCH ARTICLE

QUESTIONNAIRE-BASED EVALUATION OF THE SAFETY, USABILITY, AND PERFORMANCE OF TRUPOLY POWDER-FREE STERILE LATEX SURGICAL GLOVES

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Aseptic Condition, Dexterity, Handgrip Strength, Powder Free Latex Gloves, Usability This trial is registered at Clinical Trials Registry- India (CTRI reg. No: CTRI /2021/04/032591; registered on: 07/04/2021).

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ABSTRACT

Background: The primary goal of surgical gloves has been to aid in the attainment of aseptic conditions during a surgical procedure, assuring a higher level of protection for both the surgeon and the patient. The advent of transmissible diseases such as hepatitis B and C, and HIV, as well as the implementation of universal precautions in health-care, has prompted healthcare personnel to be concerned about their own safety, resulting in an increase in the use of latex gloves. **Methodology:** The objective of this study was to evaluate the safety and performance of Trupoly gloves by assessing the incidence of allergic reactions and usability in terms of manual dexterity, tactile sensitivity, handgrip strength, muscle activity, comfort level during usage and product complaints/issues. The questionnaire was distributed among healthcare professionals to provide their feedback and experience with the use of Trupoly gloves. **Result:** The clinical investigation was initiated on April 10, 2021 and completed on July 10, 2021. 395 responses from participating health care professionals were considered for assessment of safety and performance of the device. The results from the safety variables assessed in this Post Marketing Clinical Follow-up study indicate that about 1.01 percent of users experienced allergic reactions typical of surgical gloves made of powder-free latex. For the majority of factors related to the comfort and convenience of using Trupoly gloves, more than 85% of users reacted with scores of 04 and 05 (most comfortable). **Conclusion:** The results from this study demonstrates both the safety and performance of Trupoly gloves.

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INTRODUCTION

Since their inception in 18th century, the primary goal of surgical gloves has been to aid in the attainment of aseptic conditions during a surgical procedure, assuring a higher level of protection for both the surgeon and the patient. Since that time, gloves have been required to be worn throughout surgical procedures.^{1,2} The gloves provide two-fold protection: they decrease the rate of post-operative infections in patients and protects health-care professionals.^{3,4} The advent of transmissible diseases such as hepatitis B and C, and HIV, as well as the implementation of universal precautions in health-care, has prompted healthcare personnel's to be concerned about their own safety, resulting in an increase in the use of latex gloves.^{1,5} Latex, a natural rubber derived from *Hevea brasiliensis*, a tree native to the Amazon, is the most common material used in hand gloves.^{1,4} It has been found that natural rubber latex has excellent properties in terms of its general function, is relatively easy to wear, has good tactile properties and provides good barrier properties against the types of microorganisms associated with infections caused by surgical procedures.² "Latex gloves" have been used in healthcare settings for over 125 years. Latex gloves come in a wide range of powdered to powder-free, thin to thick, general-use to task-specific, textured to smooth, and normal to anti-microbial. Latex gloves are still used by healthcare workers because of their tear resistance, flexibility,

comfort, fit, sensitivity, durability, low cost, high tensile strength and elasticity.⁵ However, Latex sensitivity has increased with the increasing use of latex gloves. In most common situations, it manifests with irritant contact dermatitis, allergic contact dermatitis, or immediate hypersensitivity reactions (urticaria, angioedema, allergic rhinitis, asthma, or anaphylaxis).⁶ The purpose of adding powder to gloves is to make them simpler to put on and take off. Aerosolized glove powder can contain proteins that can lead to allergic reactions in the respiratory system. As an advancement, powder-free surgical gloves have been introduced into the surgical environment as a response to increased concern about latex allergy and respiratory disorders attributing to powder in the pre-powdered latex gloves among operating room personnel.⁴ The powder-free glove is coated with a polymer lining that is physically bonded to the natural rubber latex glove and acts as a lubricant to facilitate donning. This polymer material used has been determined to be entirely nonreactive, as well as being comparable in handling and donning qualities to the conventional powdered gloves.¹ Powder-free gloves have revolutionized healthcare over the past few decades and has a significant medical breakthrough because they eliminate the need for absorbable dusting powders. Healthcare professionals may now opt for powder-free gloves on the market and protect patients and themselves from the toxicity of absorbable dusting powders.⁷ This study was designed to evaluate the incidence of allergic reactions,

usability, and performance of Trupoly gloves (Sterile Latex Surgical Glove Powder Free).

METHODOLOGY

Study Design: This Clinical Investigation was conducted as a Non-Interventional, User Survey, Questionnaire-based Post Marketing Clinical Follow Up Investigation. Healthcare professionals (HCPs) from various hospitals across India were included in this survey as participants. The objectives of this clinical investigation were to evaluate the safety of Trupoly gloves (Sterile Latex Surgical Glove Powder Free), by assessing the incidence of allergic reactions as obtained through the survey conducted using a structured questionnaire and to evaluate the performance of Trupoly gloves (Sterile Latex Surgical Glove Powder Free), in India by assessing the usability in terms of manual dexterity, tactile sensitivity, handgrip strength, muscle activity, comfort level during usage and product complaints/issues. No treatment or intervention was provided to the participants. No comparator was used in this clinical investigation.

Study device: Trupoly glove (Sterile Latex Surgical Glove Powder Free) is a disposable device intended for medical purpose that is worn by operating room personnel to protect a surgical wound from contamination and to protect the personnel performing the operation from cross infection. This glove is coated with a polymer that is physically bonded to the natural rubber latex glove and acts as a lubricant to facilitate donning.

Participants: This clinical investigation was conducted with surgeons, operating theatre assistants, and other healthcare professionals from the hospitals and institutes that purchase Trupoly gloves manufactured by Healthium Medtech Limited. The questionnaire forms were provided by the sales team of Healthium Medtech Limited to the HCPs who were willing to participate in the PMCF survey study. Healthcare professionals those who are able to read and understand English, willing to provide consent for participating in this study, those who have used Trupoly gloves of Healthium Medtech Limited were included in the study. Those who were not willing to provide consent for participating in this study and have not used Trupoly gloves of Healthium Medtech Limited were excluded.

Recruitment: Consent was obtained from all the participants involved in the clinical investigation. Before filling in the questionnaire, participants were explained the rationale for conducting this investigation. Participation in this clinical investigation was voluntary. Healthcare professionals, mainly surgeons and operating theatre assistants, with experience in performing various types of surgeries, were included in the investigation as it was assumed that these personnel with vast experience of using surgical gloves could give feedback and input regarding the problems faced with various types of gloves, including Trupoly gloves.

Data Collection and management: Participants were approached in person. The clinical investigation was conducted at their place of work. It took 10–12 minutes for the participants to respond to the survey questions. All completed questionnaires were obtained as paper copies and were further scanned and archived. The questionnaire for this clinical investigation was structured so as to evaluate the safety, usability, and performance of Trupoly gloves in terms of: allergic reactions of the skin – infections and skin allergy; other allergic reactions – anaphylaxis due to latex allergy and respiratory disease due to airborne powder in the gloves; usage and quality aspects – ease of wearing, flexibility, ability to make coordinated hand and finger movements to grasp and manipulate objects (dexterity); touch perception, comfort level during usage, durability, and ease of removal.

Statistical Considerations: The total number of potential users of surgical gloves for OTs were projected to be approximately, 5,25,000, based on the survey conducted by WFSA during 2015-2016. Using

the Worthix sample size formula, responses from 384 surgeons and operation theatre assistants/ nurses were expected to provide relevant data and information for this PMCF study with a 95% confidence interval and a margin of error of 5%. Considering that the reported incidence of latex allergy among Indian healthcare professionals is 12%, survey results from 384 healthcare professionals were deemed likely to provide survey data from around 40 surgeons who have had latex allergy.

Statistical Methods & Calculations: Demographics (gender, age and number of years of using latex surgical gloves) and other data from the participants were entered and analyzed. Results are displayed in terms of the percentage of users who give each response. However, it should be noted that, not every participant answered every question, and some responses were covered by a number of points. Therefore, the percentages did not add up to 100, but gave only an indication of the relative frequency and importance of responses.

Registration and Ethical Approval: The study protocol was approved by the Institutional Ethics Committees, BGS Global Institute of Medical Sciences & Hospital, Bengaluru, and was registered in Clinical Trial Registry of India (CTRI/2021/04/032591; Registered on: 07/04/2021). The participants' privacy was maintained and all reasonable precautions were taken to prevent the disclosure of their identification details to any third party or otherwise into the public domain.

RESULTS

The clinical investigation was initiated on April 10, 2021 and completed on July 10, 2021. A total of 395 valid responses (HCPs who have used Trupoly gloves by Healthium Medtech Limited) to the survey questionnaire were collected and was included in the final dataset. These participating HCPs were from various specialties of medical sciences with broad expertise in sterile and/or surgical procedures, primarily from the departments of general surgery, orthopaedic surgery, and obstetrics & gynaecology.

Study Outcomes

Safety Endpoints: Safety of Trupoly gloves was assessed based on experience of the participants for anaphylaxis due to latex allergy, infection, skin allergy, any other adverse event or allergic reaction which could be attributed to the use of powder free latex gloves.

Performance Endpoints: Performance of Trupoly gloves was assessed based on the scores [on a scale of 1-5; (1 – least comfortable/ lowest; 5 - most comfortable/ best)] received by the participants for the seven (07) variables: Ease of wearing, Flexibility, Dexterity, Touch perception, Comfort level during usage, Durability and Ease of removal.

Demographic and relevant characteristics: A total of 395 participants were considered for further calculations. 295(74.68%) of the total participants were male, 91(23.04%) of the total number of participants were female and sex was not provided by 9(2.28%) of participants. Age of the users were divided into various age-groups in terms of their age in years, and the percentages were observed to be 26.08% for <35 years, 46.84% for 36-45 years, 21.01% for 46-55 years, 5.82% for >55 years and age group was not provided by 1(0.25%) participant. The percentage of users in terms of the number of years of latex surgical gloves usage is observed to be 22.28% used for ≤5 years, 39.75% for 5-10 years, 17.72% for 11-15 years, 20.00% for >15 years and 1 participant (0.25%) did not provide any response. The cumulative number of hours/day of use of surgical hand gloves is observed to be, 6.33% of users for <1 hour/day, 52.15% for 2-4 hours/day, 26.84% for 4-6 hours/day, 14.43% for >6 hours/day and 1(0.25%) participant did not provide any response. The usage of surgical hand gloves in terms of the approximate number of pairs per day was observed to be maximum of 55.95% users using 1-6 pairs, followed by 36.46% of users using 7-15 pairs; 4.56% of users using

Table 1. Demographic characteristics

Sl.no	Demographics		Number (%)
1	Gender	Male	295 (74.68%)
		Female	91 (23.04%)
		Not provided	9 (2.28%)
2	Age group	<35	103 (26.08%)
		36-45	185 (46.84%)
		46-55	83 (21.01%)
		>55	23 (5.82%)
		Not provided	1 (0.25%)
3	Years of using surgical gloves	≤5 years	88 (22.28%)
		5-10 years	157 (39.75%)
		11-15 years	70 (17.72%)
		>15 years	79 (20.00%)
		Not provided	1 (0.25%)
4	Use of surgical gloves (number of hours/day)	<1	25 (6.33%)
		2 to 4	206 (52.15%)
		4 to 6	106 (26.84%)
		>6	57 (14.43%)
		Not provided	1 (0.25%)
5	Use of surgical gloves (number of pairs/day)	1 - 6	221 (55.95%)
		7 - 15	144 (36.46%)
		16 - 30	18 (4.56%)
		>30	10 (2.78%)
		Not provided	1 (0.25%)
6	Use of double gloves majority	Yes	107 (27.09%)
		No	203 (51.39%)
		Not provided	85 (21.52%)
7	Wash your hands prior to donning of surgical gloves	ALWAYS	339 (85.83%)
		SOMETIMES	39 (9.87%)
		RARELY	13 (3.29%)
		Not provided	4 (1.01%)
8	Wash your hands after removing powder-free latex surgical gloves	ALWAYS	324 (82.03%)
		SOMETIMES	45 (11.39%)
		RARELY	21 (5.32%)
		Not provided	5 (1.26%)
9	Wash your hands after removing pre-powdered latex surgical gloves	ALWAYS	342 (86.58%)
		SOMETIMES	26 (6.58%)
		RARELY	9 (2.28%)
		Not provided	18 (4.56%)

Table 2. Experience with Trupoly gloves (Sterile Latex Surgical Glove Powder-Free)

Score	Number (%)						
	Ease of wearing N=395	Flexibility N=395	Dexterity N=395	Touch perception N=395	Comfort level during usage N=395	Durability N=395	Ease of removal N=395
1	0 (0)	0 (0)	1 (0.25)	0 (0)	2 (0.51)	1 (0.25)	0 (0)
2	5 (1.27)	2 (0.51)	1 (0.25)	1 (0.25)	4 (1.01)	3 (0.76)	0 (0)
3	17 (4.30)	33 (8.36)	49 (12.41)	34 (8.61)	26 (6.58)	37 (9.37)	20 (5.07)
4	153 (38.74)	150 (37.97)	151 (38.23)	167 (42.28)	155 (39.24)	151 (38.23)	149 (37.72)
5	172 (43.54)	159 (40.25)	143 (36.20)	143 (36.20)	157 (39.75)	152 (38.48)	175 (44.30)
Not provided	48 (12.15)	51 (12.91)	50 (12.66)	50 (12.66)	51 (12.91)	51 (12.91)	51 (12.91)

Score from 1-5 (1 – least comfortable/ lowest; 5- most comfortable/ best)

Table 3. Adverse Reactions associated with Surgical Gloves

Use of latex gloves can trigger allergic reactions in sensitive individuals	YES	159 (40.25%)
	NO	34 (8.61%)
	Not provided	202 (51.14%)
Powder from gloves can cause allergic reactions in sensitive individuals	YES	226 (57.21%)
	NO	18 (4.56%)
	Not provided	151 (38.23%)
Regular washing of hands after wearing latex gloves can diminish latex allergies	YES	167 (42.28%)
	NO	36 (9.11%)
	Not provided	192 (48.61%)

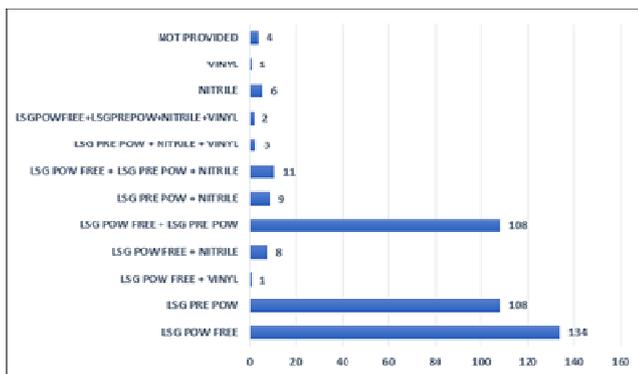
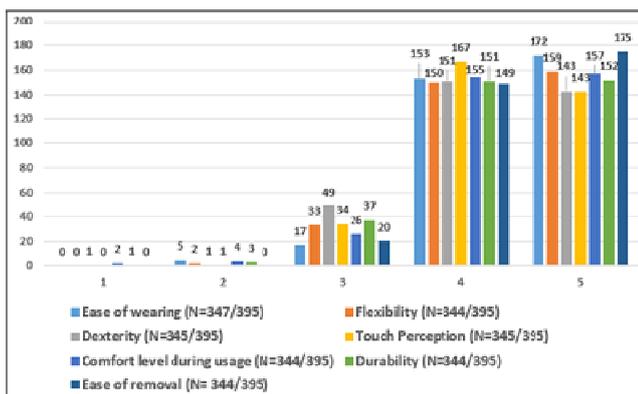


Figure 1. Material of Surgical Hand Gloves Routinely Used (N=395)



(Score 1 – least comfortable/ lowest; Score 5 – most comfortable/ best)
X-axis – Scores 1-5; Y axis - Number of participants

Figure 2. Scores received for variables of experience with Trupolygloves(N=395)

16-30 pairs, only 2.78% using more than 30 pairs per day and 1(0.25%) did not provide any response. When enquired about practising double gloving, about 27.09% of users responded "yes," and 51.39% answered "no" and another 21.51% of users did not provide any response. A total of 85.83% participants responded that they 'always' washed hands prior to donning of latex surgical gloves, 9.87% washed hands 'sometimes' while 3.29% washed hands 'rarely' and 1.01% did not provide any response. When questioned whether they washed hands after removing 'powder-free latex surgical gloves', 82.03% users mentioned that they 'always' washed hands, 11.39% 'sometimes' washed hands while 5.32% users 'rarely' washed hands and 1.26% did not provide any response. When questioned whether they washed hands after removing 'pre-powdered latex gloves', 86.58% users mentioned that they 'always' washed hands, 6.58% 'sometimes' washed hands while 2.28% users 'rarely' washed hands and 4.56% did not provide any response (Table 1). (Figure 1) represents materials of surgical hand gloves which are routinely used. Latex surgical glove powder-free was used routinely by majority of users, followed by latex surgical glove pre-powdered. A very small number of participants also informed they use nitrile gloves and vinyl gloves.

(Table 2) reported the experience with usability assessment of Trupoly gloves on the following criteria in terms of comfort and convenience under 07 characteristics namely: (1) Ease of wearing, (2) Flexibility, (3) Dexterity, (4) Touch perception, (5) Comfort level during usage, (6) Durability, and (7) Ease of removal. The scoring scale was 1–5 (1–least comfortable/lowest; 5–most comfortable/best). From among the users who provided responses (scores), more than 85% have responded with score of 04 and 05 for the variables Ease of wearing (93.66%), Flexibility (89.83%), Dexterity (85.22%), Touch perception (89.86%), Comfort level during usage (90.70%), Durability (88.08%), and Ease of removal (94.19%) (Figure 2).

Adverse reactions associated with surgical gloves: The questionnaire included a section for recording the knowledge and experience of participants to latex allergy including adverse reactions experienced by the participants and the patients. Participants were asked if they were aware of the three basic facts regarding the adverse reactions to latex gloves, viz.: (1) use of latex gloves can trigger allergic reactions in sensitive individuals, (2) powder from gloves can cause allergic reactions in sensitive individuals; and (3) regular washing of hands after wearing latex gloves can diminish latex allergies. A total of 159(40.25%) responded as being aware of the fact that use of latex gloves could trigger allergic reactions in sensitive individuals, 226(57.21%) were aware that powder from gloves could cause allergic reactions in sensitive individuals, and 167(42.28%) knew of the fact that regular washing of hands after wearing latex gloves could diminish latex allergies. (Table 3) About 4(1.01%) of users had experienced and/or witnessed adverse reactions to Trupoly gloves. These adverse reactions documented were mild allergic reaction(s) of the hands. None of the users in the present study have mentioned having experienced and/or witnessed any serious adverse reaction with Trupoly gloves.

DISCUSSION

Gloves are essential in today's healthcare practice. According to studies, non-latex surgical gloves have a higher prevalence of flaws than latex surgical gloves. Latex surgical gloves most commonly cause irritant contact dermatitis, allergic contact dermatitis, or immediate hypersensitivity reactions (urticaria, angioedema, allergic rhinitis, asthma, or anaphylaxis).⁶ Only 40.25% of 395 users responded as being aware of the fact that use of latex gloves could trigger allergic reactions in sensitive individuals. This low awareness might be because of the overall low incidence of these allergic reactions in real world situations, even when these reactions due to latex are well known and well documented in various scientific and medical literature. The same was observed in this clinical investigation. Among the 395 users, only 1.01% of users responded as having experienced and/or witnessed anaphylaxis due to latex allergy, skin allergy, any other adverse event or allergic reaction with Trupoly gloves. The adverse reactions documented in the survey questionnaire, to have been experienced with Trupoly gloves were mild reaction(s) of the hands. The adverse reactions reported were milder and less severe. The lower incidence of adverse reactions with Trupoly gloves could be deduced as to being caused by only the latex material, with no involvement of glove-powder. It has been documented in many published literature articles that in work areas, where only powder-free gloves are used, low or undetectable incidence of allergic reactions are reported. A study reported that purchasing powder-free, low-allergen gloves can maintain a number of benefits while lowering the risk of allergic reactions and type I and type IV sensitization.⁸ The adverse reactions of redness and mild allergic reaction of the hands are well-documented and attributed to the glove material, latex; and widely published in various medical and scientific literature available for latex surgical gloves. In a study conducted to determine changes in overall change in incidence of allergy with conversion to powder-free latex gloves from powdered latex gloves, it is reported that prior to glove conversion, about 44%, of the operating room staff reported symptoms related to natural rubber latex (NRL) exposure. At the end of the 14-month data collection period, only 27% reported symptoms related to NRL exposure.⁹ Airborne antigen exposure is reported to be a major source of latex sensitization among HCPs and use of powder-free latex gloves led to marked decline of 16-fold in a prospective study carried to assess latex allergen exposure and sensitization to latex among HCPs before and after an intervention (powdered latex gloves to powder-free latex gloves).¹⁰ The incidence of 1.01% of adverse reactions (mild allergic reaction of the hands) with Trupoly gloves as reported by participating HCPs in this questionnaire-based survey PMCF/ Clinical Investigation is similar and within the range of the reported data. The Powder-Free Latex Surgical Gloves are manufactured with a polymer coating and without any lubricant powder with main reason to avoid causing skin irritation due to the

powder and to avoid respiratory disorders after prolonged use due to airborne powder in individuals with asthma or breathing problems (both HCPs and patients) as well as to avoid messy appearance of the hands after removal of gloves. About 42.28% users had reported of being aware of the fact that regular washing of hands after wearing latex gloves could diminish latex allergies. However, in contrast, a lower number of participants (82.03%) washed hands after removing Powder-Free Latex Surgical Gloves. This demonstrates that users washed hands after removing the Pre-Powdered Latex Surgical Gloves mainly with the idea of washing away the powder; while washing hands after using Pre-Powdered Latex Surgical Gloves reduces not only powder-related allergies, but also diminishes allergies due to latex. About 27.09% users reported of preference towards practising double gloving. The main reasons being safety and protection as well as per the patients' requirements. A Cochrane review has shown double gloving to offer significantly more protection against inner glove perforation in surgical procedures compared to the use of a single glove layer.¹¹ More than 85% users in this study have responded with score of 04 and 05 (most comfortable) for majority of variables associated with comfort and convenience of usage of Trupoly gloves, which also corroborates with the fact that powder free latex surgical gloves are the most preferred gloves in routine surgical practice. The limitation of this clinical investigation is the data was collected through a survey questionnaire form, and there is a possibility of recall bias among the participants. However, considering the findings of this study are in line with the previously published literature, the study findings can be generalized.

CONCLUSION

According to the outcomes of the safety variables examined in this PMCF study, only 1.01 percent of users exhibited allergic reactions typical of surgical gloves made of powder-free latex. For the majority of factors related to the comfort and convenience of using Trupoly gloves, more than 85% of users reacted with scores of 04 and 05 (most comfortable). This demonstrates the effectiveness and safety of Trupoly gloves (Sterile Latex Surgical Glove Powder Free).

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Data Availability Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Statement and Declarations

Authors AKM and DTS are the employees of Healthium Medtech Limited, Bangalore, India who are manufactures of Trupoly gloves. Authors DS, DMG, and PY declares no conflict of interest.

KEYPOINTS

- Gloves are essentials in today's healthcare Practice.
- The primary goal of surgical gloves has been to aid in the attainment of aseptic conditions during a surgical procedure, assuring a higher level of protection for both the surgeon and the patient.

- The powder-free surgical glove is coated with a polymer lining that is physically bonded to the natural rubber latex glove and acts as a lubricant to facilitate donning.
- Powder-free surgical gloves have been introduced into the surgical environment as a response to increased concern about latex allergy and respiratory disorders attributing to powder in the pre-powdered gloves among operating room personnel.

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