

Original Research Article

Assessment of safety, usability and performance of sterile latex surgical glove pre-powdered of Healthium Medtech limited: a survey study based on questionnaire

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ABSTRACT

Background: Medical gloves worn during patient examinations and procedures aids in the reduction of cross-contamination between healthcare professionals and patients. Gloves have to be strong enough to protect the wearer and comfortable enough not to choke the hand of the user. The aim of the study was to assess the incidence of allergic reactions, usability, and performance of Truskin gloves (Sterile latex surgical glove pre-powdered).

Methods: The objective of this study was to evaluate the safety and performance of Truskin 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. Consent was obtained from all the participants (healthcare professionals from various hospitals across India) involved in the study. The questionnaire was distributed among healthcare professionals to provide their feedback and experience with use of Truskin gloves.

Results: The clinical investigation was initiated on April 10, 2021 and completed on July 10, 2021. Responses from 472 participating health care professionals were considered for assessment of safety and performance of Truskin gloves. The results from the safety variables assessed in this study indicate that about 5.51% users had experienced allergic reactions typical of powdered latex surgical gloves. More than 80% users have responded with a score of 04 and 05 (most comfortable) for all the variables associated with comfort and convenience of usage of Truskin gloves.

Conclusions: The results from this study demonstrates both the safety and performance of Truskin gloves.

Keywords: Allergic reaction, Anaphylaxis, Handgrip strength, Latex surgical gloves, Tactile sensitivity

INTRODUCTION

Medical gloves worn during procedures and examinations have become essential for hygienic practice. The use of these disposable protective gloves during patient examinations and procedures aids in the reduction of cross-contamination between healthcare professionals and patients.

Research has shown that gloves, when worn, significantly lower the risk of viral transmission and increase the ability to diagnose and treat certain diseases. In the long

run, all healthcare professionals play a crucial role in controlling disease spread, a task that requires sanitation at every level.¹

Surgical and medical examination gloves are the two different kinds of medical gloves available. Surgical gloves are sterile, whereas medical examination gloves are either sterile or non-sterile. The main reason surgical gloves are used is because of the increased safety precautions that go along with any surgical procedure. The essential requirements for surgical gloves: they must meet the customer's unique requirements for durability,

flexibility, tactile sensitivity, resiliency, and must fit like a "second skin" for surgeons performing delicate procedures, must be strong enough to protect the wearer and comfortable enough not to choke the hand of the user, and at the same time, the material must meet demanding production criteria as well as tactile requirements. The ideal glove, therefore, is the one that conforms exactly to the user's needs, supplying extraordinary dexterity while protecting sensitive tissues. Given the importance of the surgical procedure, proper surgical gloves must be used at all times. These gloves have a more accurate size range than medical examination gloves. Medical examination gloves are usually used during procedures that do not require sterile conditions, such as drawing blood for a blood test. Gloves may also protect the wearer from damage caused by harmful chemicals.^{2,3}

The need for protection against HIV and hepatitis B and C viruses and the introduction of universal precautions in the health-care industry led to an upsurge in latex glove usage among health care workers.³ Latex, nitrile, polyvinyl chloride, and neoprene are some of the most common surgical glove materials.⁴

Gloves made from latex provide more protection when compared with those made from other materials where there can be a chance of leakage thus exposing the skin of the surgeons and other healthcare professionals to the infection. "Latex gloves" have been used in a healthcare setting for over 125 years. Latex gloves are readily available, affordable, and highly effective in protecting healthcare workers from infectious microorganisms and are commonly used in various healthcare settings. It offers a wide range of protection, which is ideal for use in many healthcare procedures. Surgical latex gloves come in a range of powdered to powder-free, general-use to task-specific, textured to smooth, thin to thick, and normal to antimicrobial.³

Corn starch is used to make the latex gloves more lubricant, making it easy for donning. The powder used in the gloves provide better grip while working. These gloves provide better grip than the gloves without powder or corn starch. However, with the continued usage of latex surgical gloves, latex sensitivity is an issue.⁵

Glove manufacturers have made significant advancements and improvements, producing a wide range of high-quality gloves. Even with all of the high-tech production, mechanical stress, the type of surgery, the number of tools used in the surgical case, the length of the surgical procedure, and the wearer's role in the surgical case are all factors that enhance the chance of glove failure during use.⁶

This study was planned to assess the incidence of allergic reactions, usability, and performance of Truskin gloves (Sterile latex surgical glove pre-powdered) and to

understand the reasons why latex gloves are popular among healthcare professionals.

METHODS

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 study was to clinically investigate were to evaluate the safety of Truskin gloves (Sterile latex surgical glove pre-powdered), by assessing the incidence of allergic reactions as obtained through the survey conducted using a structured questionnaire and to evaluate the performance of Truskin (Sterile latex surgical glove pre-powdered), 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

Truskin gloves (Sterile latex surgical glove pre-powdered) 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 lightly powdered with dusting powder USP corn starch for easy donning.

Participants

This clinical investigation was conducted with surgeons, operating theatre assistants, and other healthcare professionals from the hospitals and institutes that purchase Truskin 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 post market clinical followup (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 Truskin gloves of Healthium Medtech Limited were included in the study. Those who were not willing to provide consent for participating in this study and those who have not used Truskin gloves of Healthium Medtech Limited were excluded.

Valid and complete responses to the questionnaire designed for Truskin gloves by Healthium Medtech Limited, were collected.

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. Participants were included in this investigation only when they agreed to provide consent to participate.

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 Truskin gloves, and also provide the reason for their preference of one type of glove over the others.

Data collection and management

Participants were approached by e-mail and 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 questionnaires were reviewed to identify missing data or discrepancies. Data queries were raised for missing data and discrepancies were resolved appropriately. All completed questionnaires were obtained as paper copies and were further scanned and saved on the share point of Healthium Medtech Limited's clinical affairs team.

The questionnaire for this clinical investigation was structured so as to evaluate the safety, usability, and performance of Truskin 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; and 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

Sample size calculation

Sample size was calculated using the Worthix sample size formula. The total number of potential users of surgical gloves for OTs were projected to be approximately, 5,25,000, based on the following: According to a survey conducted by WFSA during 2015-2016, total number of general surgeons in India was 31,560. Considering an approximate increase of around 10% in last 5 years, total number of surgeons in India were estimated to be around 35,000. Considering a similar number for (1) orthopaedic surgeons and (2)

obstetrics and gynaecology surgeons, total number of surgeons were estimated to around 1,05,000. Further, by considering additional 4 times more personnel in the operation theatres (OT), like OT assistants and nurses who usually use surgical gloves extensively in the OT, number of additional OT staff was calculated as approximately 4,20,000. 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 and 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 committee, BGS global institute of medical sciences and 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 472 valid responses (HCPs who have used Truskin gloves by Healthium Medtech Limited) to the survey questionnaire were collected and 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 and gynaecology.

Study outcomes

Safety endpoints

Safety of Truskin gloves was assessed based on experience of the participants for anaphylaxis due to latex

allergy, respiratory disease due to airborne powder in the gloves, infection, skin allergy, any other adverse event or allergic reactions which could be attributed to the use of these pre-powdered latex gloves.

Performance endpoints

Performance of Truskin 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 472 participants were considered for further calculations.

The 352 (74.58%) of the total number of participants were male, 110 (23.30%) of the total number of participants were female and sex was not provided by 10 (2.12%) 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 22.04% for <35 years, 48.73% for 36-45 years, 22.03% for 46-55 years, 6.99% for >55 years and age group was not provided by 1 (0.21%) participant. The percentage of users in terms of the number of years of latex surgical gloves usage is observed to be 19.91% used for ≤5 years, 40.26% for 5-10 years, 19.49% for 11-15 years and 20.34% using for >15 years. The cumulative amount of hours/day of use of surgical hand gloves is observed to be, 6.99% of users used for <1 hour/day, 51.48% for 2-4 hours/day, 28.18% for 4-6 hours/day, 13.13% for >6 hours/day and 1 participant (0.21%) 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 for 1-6 pairs by 56.99% users, followed by 35.38% of users using 7-15 pairs; 5.51% of users using 16-30 pairs, only 1.91% using more than 30 pairs per day and 1 (0.21%) user did not provide any response. When enquired about practising double gloving, about 30.51% of users responded "yes," and 50.21% answered "no," and another 19.28% of users did not provide any response.

A total of 85.59% participants responded that they “always” washed hands prior to donning of latex surgical gloves, 11.66% washed hands “sometimes”, while 2.54% washed hands “rarely”. When questioned whether they washed hands after removing ‘pre-powdered latex surgical gloves’, 88.98% users mentioned that they “always” washed hands, 8.69% “sometimes” washed hands while 1.91% users ‘rarely’ washed hands and 0.42% did not provide any response. When questioned whether they washed hands after removing ‘powder-free latex surgical gloves’, 72.88% users mentioned that they “always” washed hands, 13.14% “sometimes” washed hands while 6.14% users ‘rarely’ washed hands and 7.84% did not provide any response (Table 1).

Figure 1 represents materials of surgical hand gloves which are routinely used. Latex surgical glove pre-powdered was used routinely by majority of users, followed by powder free gloves. A very small number of participants also informed they use nitrile gloves and vinyl gloves. Table 2 reported the experience with usability assessment of Truskin 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 80% have responded with score of 04 and 05 for all the variables-Ease of wearing (88.24%), flexibility (87.81%), dexterity (81.14%), Touch perception (85.32%), comfort level during usage (86.16%), durability (81.71%), and ease of removal (91.91%) (Figure 2).

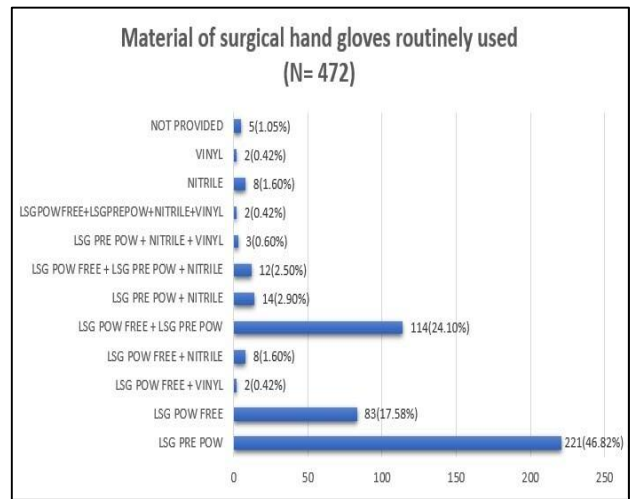


Figure 1: Material of surgical hand gloves routinely used, (n=472).

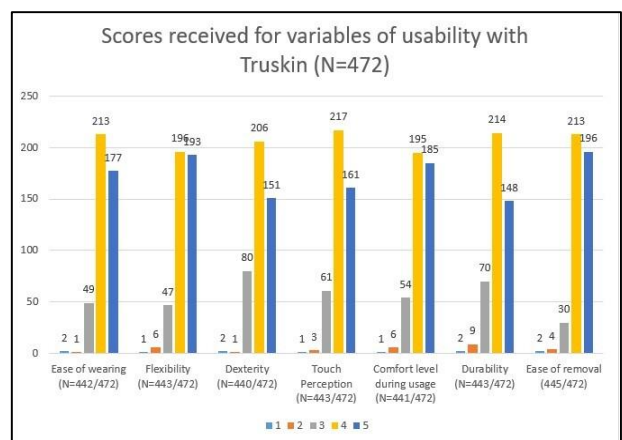


Figure 2: Scores received for variables of usability with Truskin gloves, (n=472).

(1-least comfortable/ lowest; 5-most comfortable/ best), x-axis= scores; y-axis= % of participants.

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 213 (45.12%)

responded as being aware of the fact that use of latex gloves could trigger allergic reactions in sensitive individuals, 306 (64.83%) were aware that powder from gloves could cause allergic reactions in sensitive individuals, and 218 (46.18%) knew of the fact that regular washing of hands after wearing latex gloves could diminish latex allergies (Table 3). About 26 (5.51%) users had experienced and/or witnessed adverse event/allergic reaction to Truskin gloves. These adverse reactions documented were related to itching, allergic reaction, contact dermatitis, rash, and roughness of skin on hands. None of users in present study mentioned having experienced and/ or witnessed any serious adverse reaction with Truskin gloves.

Table 1: Patient demographics.

Demographics	Number (%)	
Gender	Male	352 (74.58)
	Female	110 (23.30)
	Not provided	10 (2.12)
Age group (years)	<35	104 (22.04)
	36-45	230 (48.73)
	46-55	104 (22.03)
	>55	33 (6.99)
	Not provided	1 (0.21)
Years of using surgical gloves (years)	≤5	94 (19.91)
	5-10	190 (40.26)
	11-15	92 (19.49)
	>15	96 (20.34)
Use of surgical gloves (number of hours/day)	<1	33 (6.99)
	2 to 4	243 (51.48)
	4 to 6	133 (28.18)
	>6	62 (13.13)
	Not provided	1 (0.21)
Use of surgical gloves (number of pairs/day)	1-6	269 (56.99)
	7-15	167 (35.38)
	16-30	26 (5.51)
	>30	9 (1.91)
	Not provided	1 (0.21)
Use of double gloves majority	Yes	144 (30.51)
	No	237 (50.21)
	Not provided	91 (19.28)
Wash your hands prior to donning of surgical gloves	Always	404 (85.59)
	Sometimes	55 (11.66)
	Rarely	12 (2.54)
	Not provided	1 (0.21)
Wash your hands after removing pre-powdered latex surgical gloves	Always	420 (88.98)
	Sometimes	41 (8.69)
	Rarely	9 (1.91)
	Not provided	2 (0.42)
Wash your hands after removing powder free latex surgical gloves	Always	344 (72.88)
	Sometimes	62 (13.14)
	Rarely	29 (6.14)
	Not provided	37 (7.84)

Table 2: Experience with Truskin gloves, (n=472).

Score	Number (%)						
	Ease of wearing	Flexibility	Dexterity	Touch perception	Comfort level during usage	Durability	Ease of removal
1	2 (0.42)	1 (0.21)	2 (0.42)	1 (0.21)	1 (0.21)	2 (0.42)	2 (0.42)
2	1 (0.21)	6 (1.27)	1 (0.21)	3 (0.64)	6 (1.27)	9 (1.91)	4 (0.85)
3	49 (10.38)	47 (9.96)	80 (16.95)	61 (12.92)	54 (11.44)	70 (14.83)	30 (6.36)
4	213 (45.13)	196 (41.53)	206 (43.65)	217 (45.98)	195 (41.31)	214 (45.34)	213 (45.13)
5	177 (37.50)	193 (40.89)	151 (31.99)	161 (34.11)	185 (39.20)	148 (31.36)	196 (41.52)
Not provided	30 (6.36)	29 (6.14)	32 (6.78)	29 (6.14)	31 (6.57)	29 (6.14)	27 (5.72)

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

Table 3: Awareness regarding the adverse reactions with surgical gloves.

Variables	Truskin	
	Adverse reaction experience	Number (%)
Use of latex gloves can trigger allergic reactions in sensitive individuals	Yes	213 (45.13)
	No	33 (6.99)
	Not provided	226 (47.88)
Powder from gloves can cause allergic reactions in sensitive individuals	Yes	306 (64.83)
	No	16 (3.39)
	Not provided	150 (31.78)
Regular washing of hands after wearing latex gloves can diminish latex allergies	Yes	218 (46.19)
	No	31 (6.57)
	Not provided	223 (47.24)

DISCUSSION

In today's health care practice, with the introduction of universal precautions in the health-care industry the use of gloves is indispensable. However, with the rising usage of latex surgical gloves, latex sensitivity is an issue. In most common situations, it manifests with irritant contact dermatitis, allergic contact dermatitis, or immediate hypersensitivity reactions (urticaria, angioedema, allergic rhinitis, asthma, or anaphylaxis).⁵

In this study, a total of 45.13% of these 472 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. Same observed in this clinical investigation. Among 472 users, a total of only 5.51% of users responded having had experienced and/or witnessed anaphylaxis due to latex allergy, skin allergy, any other adverse event or allergic reaction with Truskin gloves.

The adverse reactions documented in the survey questionnaire, to have been experienced with Truskin gloves were primarily related to itching, roughness and

redness of the hands. The reactions could be attributed to both latex material as well as to the powder used. These adverse reactions are widely published in various medical and scientific literature available for pre-powdered latex surgical gloves. A study published shows that in a study population consisting of 1040 medical, surgical, and laboratory workers evaluated for prevalence of latex related symptoms and sensitization with powdered medical gloves, symptoms of adverse reaction related to latex were noticed in 21.8% of the population studied.⁸ Another study reported similar adverse reactions with latex in about 6.2% of the participants.⁹ An incidence of about 3.3% symptoms suggestive of latex allergy such as urticaria, rhinitis, wheeze and asthma, and a higher percentage (30.9%) of glove-related symptoms (glove dermatitis (GD)) have also been retrieved from published literature.¹⁰ The incidence of 5.51% of adverse reactions with Truskin gloves as reported by participating HCPs in this questionnaire-based survey PMCF/ clinical investigation is similar and within the range of the reported data. Among the users, even though 64.83% were aware that powder from gloves could cause allergic reactions in sensitive individuals, percent difference in usage of pre-powdered latex surgical gloves and powder-free latex surgical gloves respectively, was high (46.82% versus 17.58%, respectively). This may be because of ease of donning and convenience of flexibility of fingers and low incidence of tearing with pre-powdered latex surgical gloves while conducting surgical procedures, and hence a preference towards usage of same.

About 46.19% users had reported of being aware of the fact that regular washing of hands after wearing latex gloves could diminish latex allergies. This was found to correlate with the number of users, about 88.98% from this group of participants who "always" washed hands after removing pre-powdered latex surgical gloves. However, in contrast, a lower number of participants (72.88%) washed hands "always" 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 gloves reduces not only powder-related allergies, but also diminishes allergies due to latex. About 30.51% 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 80% users in this study have responded with score of 04 and 05 (most comfortable) for all variables associated with comfort and convenience of usage of Truskin gloves, which also corroborates with the fact that pre-powdered 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

The results from the safety variables assessed in this PMCF study indicate that about 5.51% users had experienced allergic reactions typical of powdered latex surgical gloves. More than 80% of users have responded with a score of 04 and 05 (most comfortable) for all the variables associated with comfort and convenience of usage of Truskin gloves. Hence, the results from this PMCF study, conducted as a questionnaire-based survey among healthcare professionals, demonstrates both the safety and performance of Truskin gloves (Sterile latex surgical glove pre-powdered).

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Conflict of interest: Authors Moharana A. K. and Deepak T. S. are the employees of Healthium Medtech Limited, Bangalore, India who are manufactures of Truskin gloves. Authors Dayananda S., Dinesh M. G., Yaji P. declares no conflict of interest

Ethical approval: The study was approved by the Institutional Ethics Committee, Reg. No: CTRI/2021/04/032591.

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