

A Comparative Study to Evaluate Safety and Performance of Sterile Surgical Gloves

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Abstract: ***Objective:** Evaluate and compare the safety and performance of four types of sterile surgical gloves: orthopaedic gloves, powder - free polychloroprene gloves, polymer - coated gloves, and powdered latex surgical gloves. **Methods:** Observational trial involving 100 surgeons and surgical staff using four types of sterile surgical gloves across 2400 glove uses. Data on glove integrity, user comfort, tactile sensitivity, adverse reactions, and overall satisfaction were collected. **Results:** All glove types demonstrated good barrier protection with no reported infections. User satisfaction was high for all the gloves, with Neoprene Soft and Premier receiving the highest ratings for comfort, fit, and flexibility. Powdered latex gloves received a "Good" rating but showed a higher prevalence of double gloving among surgeons. **Conclusion:** All four sterile surgical glove types provided adequate protection against pathogens. Non - latex gloves offered superior user comfort and flexibility compared to powdered latex gloves. The study highlights the importance of considering user preference and potential latex allergies when selecting surgical gloves.*

Keywords: surgical gloves, sterile gloves, latex, glove safety, glove performance

1. Introduction

Sterile surgical gloves have been recognized as a critical component in the infection control protocols within surgical environments, serving as a barrier against the transmission of pathogens between healthcare workers and patients.¹ The development of surgical gloves has led to the introduction of various types, including orthopaedic gloves, powder - free polychloroprene gloves, polymer - coated gloves, and powdered latex surgical gloves. These variants have been differentiated based on their material composition, texture, thickness, and elasticity, which are believed to influence their barrier effectiveness, tactile sensitivity, and overall user satisfaction.²

The motivation for this research was driven by the necessity to understand the relative safety and performance of these different glove types in a clinical setting. Such knowledge is

pivotal in guiding healthcare professionals in selecting the most appropriate gloves, thereby optimizing infection control and enhancing surgical procedure outcomes.^{3, 4}

2. Aims

The primary aim of this research was to evaluate and compare the safety and performance of four types of sterile surgical gloves: orthopaedic gloves, powder - free polychloroprene gloves, polymer - coated gloves, and powdered latex surgical gloves. The specific objectives were:

The study aimed to comprehensively evaluate various aspects of sterile surgical gloves to ensure their efficacy and safety in clinical settings. This included assessing the barrier effectiveness of each glove type against blood - borne pathogens which is crucial for preventing the transmission of infectious diseases during surgical procedures. Additionally,

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the tactile sensitivity provided by each glove type during surgical interventions was evaluated. The research also delved into the incidence of allergic reactions or dermatitis associated with each type of glove as adverse reactions can significantly impact healthcare workers' well-being and efficiency. Furthermore, the study compared user satisfaction and comfort levels for each glove type during extended surgical procedures to understand how glove comfort and fit affect surgical performance and the overall user experience.

3. Methods

1) Study Design

This study was conducted as an observational trial to evaluate the safety and performance of four types of sterile surgical gloves manufactured by Kanam Latex Industries Pvt. Ltd., Tamil Nadu, India namely

- Sterile Latex Surgical Gloves, Powder free (for orthopaedic use) - Surgicare® Ortho
- Sterile Latex Surgical Gloves, Powder free (Polymer coated) - Surgicare® Premier
- Sterile Latex Surgical Gloves, Powdered - Surgicare®
- Sterile Non - Latex Surgical Gloves, Powder free - Surgicare® Neoprene Soft

Unlike a crossover trial, this observational approach allowed for the assessment of each glove type under routine clinical conditions without manipulating the order of glove use. This design was chosen to reflect real-world usage and to minimize experimental bias.

2) Participants

The participant pool included 100 surgeons and surgical staff from the medical college's affiliated hospitals. These individuals were selected based on their regular engagement in surgical procedures. The key eligibility criterion was the absence of known allergies to the materials comprising the gloves, ensuring that reactions, if any, were due to the gloves used during the study period and not pre-existing conditions.

3) Glove Allocation and Usage

In total, 2400 gloves were used throughout the study, with 600 instances of use allocated to each glove type. This allocation ensured a balanced comparison across the different glove categories, allowing for a comprehensive assessment of each glove's safety and performance. The gloves were distributed among the participants based on their routine surgical schedules, with no specific sequence enforced, to maintain the observational nature of the study.

4) Data Collection

Data were collected through direct observation and participant feedback during and after surgical procedures.

Observational metrics included glove integrity (noting any tears or punctures), while participant feedback focused on tactile sensitivity, comfort, and any adverse reactions such as allergic responses or skin irritation. This information was recorded systematically for each glove use, accumulating a robust dataset for analysis.

5) Statistical Analysis

The analysis aimed to compare the four glove types across various safety and performance parameters. Descriptive statistics were used to summarize the observed outcomes, such as the frequency of glove failures and reported discomfort levels.

4. Results

Sterile Latex Surgical Gloves, Powder free (for orthopaedic use) - Surgicare® Ortho

In a comprehensive clinical investigation involving 600 cases, a notable gender disparity was observed with 68% male and 32% female subjects utilizing surgical gloves across various age groups. The majority of glove usage fell within the 41 - 60 years age bracket, making up 37% of the total. The distribution of surgery durations was weighted towards shorter procedures, with 48% lasting 1 - 2 hours and a smaller fraction extending to 3 - 4 hours. The study's broad demographic reach and varied procedure lengths provided a robust dataset for evaluating the gloves' performance in a clinical setting.

User engagement in the study was well-represented across the medical staff, with 120 nurses and 480 surgical practitioners (240 surgeons and 240 co-surgeons) providing feedback. The glove sizes utilized were predominantly 7 inches and 7.5 inches, indicating a standard range of fits for the clinical personnel. This distribution highlights the importance of offering a range of glove sizes to accommodate the diverse needs of healthcare professionals in surgical environments.

The clinical outcomes reported by the users indicated a consistent 'Good' rating across multiple performance parameters, with all groups rating the comfort, ease of handling objects, task efficiency, glove material quality, and flexibility at a mean of 4 out of 5. Additionally, the gloves rated well in tactile sensation and fit. These positive assessments were capped off with a high overall product satisfaction rating of 9, signifying user contentment with the gloves' performance and reinforcing their suitability for various surgical applications.

Table 1: Subject Demographics and Surgery Duration

| Description | Total Subjects | Female | Male | Age 1 - 20 | Age 21 - 40 | Age 41 - 60 | Age 61 - 80 | Age >80 | 1 - 2 hrs | 2 - 3 hrs | 3 - 4 hrs |
|------------------------------|----------------|--------|------|------------|-------------|-------------|-------------|---------|-----------|-----------|-----------|
| Number of Subjects/Use Cases | 600 | 190 | 410 | 50 | 175 | 225 | 145 | 5 | 290 | 245 | 65 |
| Percentage | - | 32% | 68% | 8% | 30% | 37% | 24% | 1% | 48% | 41% | 11% |

Table 2: User Profile and Glove Usage

| User Type | Number of Users | Glove Size 6.5" | Glove Size 7" | Glove Size 7.5" |
|---------------|-----------------|-----------------|---------------|-----------------|
| Nurse | 120 | 195 (32%) | 228 (38%) | 177 (30%) |
| Surgeons | 240 | - | - | - |
| Co - Surgeons | 240 | - | - | - |

Table 3: Clinical Investigation Outcomes

| Performance Parameter | Surgeons Mean Rating | Co - Surgeon Mean Rating | Nurse Mean Rating | Overall Mean Rating |
|-------------------------------------|----------------------|--------------------------|-------------------|---------------------|
| Comfort of Using Gloves | 4 | 4 | 4 | 4 |
| Ease of Handling Small Objects | 4 | 4 | 4 | 4 |
| Tasks Without Hindrance | 4 | 4 | 4 | 4 |
| Glove Material | 4 | 4 | 4 | 4 |
| Flexibility of Gloves | 4 | 4 | 4 | 4 |
| Tactile (Touch Sensation) | 4 | 4 | 4 | 4 |
| Fit of Glove in Hands | 4 | 4 | 4 | 4 |
| Overall Product Satisfaction Rating | 9 | 9 | 9 | 9 |

Sterile Non - Latex Surgical Gloves, Powder free - Surgicare® Neoprene Soft

The clinical investigation encompassed 600 subjects, displaying a gender distribution of 32% female and 68% male participants across a wide age range, with a significant number of procedures falling within the 1 - 2 and 2 - 3 hours duration, accounting for 33% and 48% respectively. The demographic spread provided a comprehensive basis for evaluating the surgical gloves, with the largest age groups being 21 - 40 and 41 - 60 years old, representing 37% and 33% of the subjects. This wide age and gender distribution, coupled with the varied duration of surgeries, offered a robust dataset for assessing glove performance in real - world clinical settings.

Feedback from users including 120 nurses and 480 surgical practitioners (240 surgeons and 240 co - surgeons) highlighted a high level of satisfaction with glove sizes predominantly being 6.5 inches to 7.5 inches. The clinical safety and performance evaluation yielded an 'Excellent' overall rating, with a mean performance rating of 5 across key parameters such as glove fit, flexibility, and protection against pathogens. Both the surgical staff and nurses reported no difficulties in wearing the gloves, ensuring compliance with infection prevention protocols. The high overall product satisfaction scores, 10 for nurses and co - surgeons and 9 for surgeons, underscored the gloves' efficacy and user satisfaction in clinical environments, affirming their suitability for a range of surgical applications.

Table 4: Subject Demographics and Surgery Duration

| Description | Total Subjects | Female | Male | Age 1 - 20 | Age 21 - 40 | Age 41 - 60 | Age 61 - 80 | Age >81 | 1 - 2 hrs | 2 - 3 hrs | 3 - 4 hrs |
|--------------------|----------------|--------|------|------------|-------------|-------------|-------------|---------|-----------|-----------|-----------|
| Number of Subjects | 600 | 190 | 410 | 65 | 220 | 200 | 110 | 5 | 200 | 285 | 115 |
| Percentage | - | 32% | 68% | 11% | 37% | 33% | 18% | 1% | 33% | 48% | 19% |

Table 5: User Feedback and Glove Size Distribution

| User Type | Number of Users | Glove Size 6.5" | Glove Size 7" | Glove Size 7.5" | Overall Rating |
|---------------|-----------------|-----------------|---------------|-----------------|----------------|
| Nurse | 120 | 193 (32%) | 223 (37%) | 184 (31%) | 10 |
| Surgeons | 240 | - | - | - | 9 |
| Co - Surgeons | 240 | - | - | - | 10 |

Table 6: Clinical Safety and Performance Evaluation

| Performance Parameter | Surgeons | Co - Surgeons | Nurse | Overall Rating |
|-------------------------------|----------|---------------|-------|----------------|
| Strong Grip | Yes | Yes | N/A | - |
| Reduction of Hand Fatigue | Yes | Yes | N/A | - |
| Double Gloving | Yes | Yes | N/A | - |
| Glove Fit | Yes | Yes | Yes | - |
| Flexibility | Yes | Yes | N/A | - |
| Protection Against Pathogens | Yes | Yes | Yes | - |
| Difficulty Wearing Gloves | No | No | No | - |
| Protection from Contamination | Yes | Yes | Yes | - |
| IFU Compliance | Yes | Yes | Yes | - |
| Mean Performance Rating | 5 | 5 | 5 | 5 |
| Overall Product Satisfaction | 9 | 10 | 10 | 10 |

Sterile Latex Surgical Gloves, Powder free (Polymer coated) - Surgicare® Premier:

In a thorough clinical investigation involving 600 participants, the distribution of subjects by gender was 32% female and 68% male, spanning a broad age spectrum. Notably, a significant proportion of the surgical procedures

lasted between 1 to 2 hours and 2 to 3 hours, making up 33% and 48% of the cases respectively. The age demographics primarily fell within the 21 - 40 and 41 - 60 year ranges, constituting 37% and 33% of the participants. This diverse participant profile, along with the variation in surgery durations, furnished a solid foundation for a comprehensive

assessment of the surgical gloves' performance across different clinical scenarios.

User feedback, sourced from 120 nurses and 480 surgical professionals (comprising 240 surgeons and 240 co - surgeons), revealed substantial satisfaction with the glove sizes, which mainly ranged between 6.5 to 7.5 inches. The clinical safety and performance assessment of the gloves received an outstanding overall rating, with a perfect mean

performance score of 5 in crucial areas such as glove fit, flexibility, and pathogen protection. The absence of any reported difficulties in glove usage by both nurses and surgical staff highlights the gloves' compliance with infection control standards. Exceptionally high satisfaction ratings, with a perfect score of 10 from nurses and co - surgeons and a near - perfect score of 9 from surgeons, reflect the gloves' high efficacy and acceptance in clinical settings, confirming their appropriateness for various surgical procedures.

Table 7: Subject Demographics and Surgery Duration

| Description | Total Subjects | Female | Male | Age 1 - 20 | Age 21 - 40 | Age 41 - 60 | Age 61 - 80 | >81 Years | 1 - 2 hrs | 2 - 3 hrs | 3 - 4 hrs |
|--------------------|----------------|--------|------|------------|-------------|-------------|-------------|-----------|-----------|-----------|-----------|
| Number of Subjects | 600 | 31 | 569 | 90 | 265 | 160 | 85 | N/A | 155 | 285 | 160 |
| Percentage | - | 5% | 95% | 15% | 44% | 27% | 14% | N/A | 26% | 47% | 27% |

Table 8: User Profile and Glove Size Distribution

| User Type | Number of Users | Glove Size 7" | Glove Size 7.5" |
|---------------|-----------------|---------------|-----------------|
| Nurse | 120 | 312 (52%) | 288 (48%) |
| Surgeons | 240 | - | - |
| Co - Surgeons | 240 | - | - |

Table 9: Clinical Safety and Performance Evaluation

| Performance Parameter | Surgeons | Co - Surgeons | Nurse | Mean Rating |
|-------------------------------|----------|---------------|-------|-------------|
| Strong Grip | Yes | Yes | N/A | - |
| Reduction of Hand Fatigue | Yes | Yes | N/A | - |
| Use of Double Layer of Gloves | 149 | 156 | N/A | - |
| Glove Fit | Yes | Yes | Yes | - |
| Flexibility | Yes | Yes | N/A | - |
| Protection Against Pathogens | Yes | Yes | Yes | - |
| Difficulty Wearing Gloves | No | No | No | - |
| IFU Compliance | Yes | Yes | Yes | - |
| Mean Performance Rating | 4 | 4 | 4 | 4 |
| Overall Product Satisfaction | N/A | N/A | N/A | N/A |

Sterile Latex Surgical Gloves, Powdered - Surgicare®

The clinical investigation involving 600 subjects using Powdered Sterile Latex Surgical Gloves yielded comprehensive data on usage and satisfaction. The gender distribution was significantly skewed towards male subjects, with 525 male participants (87%) and 75 female participants (13%). The age range of subjects was diverse, spanning from below 1 year to above 80 years, with the majority falling within the 21 - 40 years bracket (34%). A wide range of procedures was conducted, emphasizing the gloves' applicability across various surgical scenarios. The glove sizes used mostly ranged from 7 to 7.5 inches, catering to the majority of the users, which included 120 nurses, 240 surgeons, and 240 co - surgeons.

In terms of product quality, all professional users agreed that the gloves met the necessary standards, indicating satisfaction with the gloves' strong grip, fit, and flexibility. Interestingly, while a significant proportion of surgeons and co - surgeons utilized double layering of gloves, the clinical safety

parameters were positively evaluated across all 600 use cases. The gloves provided adequate protection against pathogens, and there were no difficulties reported with wearing them. Furthermore, no post - surgical infections or allergies were reported by any of the subjects, highlighting the gloves' efficacy in maintaining clinical safety.

The clinical performance of the Powdered Sterile Latex Surgical Gloves was rated as 'Good' across various parameters, with a mean rating of 4 on a 5 - point Likert scale. Parameters such as comfort, ease of handling objects, and the ability to perform tasks without hindrance all received favorable ratings. The functional performance, including tactile sensation and the fit of the glove, also received a 'Good' rating. Complications were non - existent among the users, and overall product satisfaction was high, with a mean satisfaction rating of 9 out of 10. These results affirm the gloves' high - quality performance and user satisfaction in a clinical setting.

Table 10: Subject Demographics and Surgery Duration

| Description | Total Subjects | Female | Male | < 1 Year | 1 - 20 Years | 21 - 40 Years | 41 - 60 Years | 61 - 80 Years | > 80 Years | 1 - 2 hrs | 2 - 3 hrs | 3 - 4 hrs |
|--------------------|----------------|--------|------|----------|--------------|---------------|---------------|---------------|------------|-----------|-----------|-----------|
| Number of Subjects | 600 | 75 | 525 | 5 | 90 | 205 | 160 | 125 | 15 | 435 | 134 | 31 |
| Percentage | - | 13% | 87% | 1% | 15% | 34% | 27% | 20% | 3% | 73% | 22% | 5% |

Table 11: User Profile and Glove Size Distribution

| User Type | Number of Users | Glove Size 6" | Glove Size 6.5" | Glove Size 7" | Glove Size 7.5" | Glove Size 8" |
|---------------|-----------------|---------------|-----------------|---------------|-----------------|---------------|
| Nurse | 120 | 26 (5%) | 41 (7%) | 231 (38%) | 268 (45%) | 34 (5%) |
| Surgeons | 240 | - | - | - | - | - |
| Co - Surgeons | 240 | - | - | - | - | - |

Table 12: Clinical Safety and Performance Evaluation

| Performance Parameter | Surgeons | Co - Surgeons | Nurse | Mean Rating |
|-------------------------------|----------|---------------|-------|-------------|
| Strong Grip | Yes | Yes | N/A | - |
| Reduction of Hand Fatigue | Yes | Yes | N/A | - |
| Use of Double Layer of Gloves | Yes | Yes | N/A | - |
| Glove Fit | Yes | Yes | Yes | - |
| Flexibility | Yes | Yes | N/A | - |
| Protection Against Pathogens | Yes | Yes | Yes | - |
| Difficulty Wearing Gloves | No | No | No | - |
| IFU Compliance | Yes | Yes | Yes | - |
| Mean Performance Rating | 4 | 4 | 4 | 4 |
| Overall Product Satisfaction | 9 | 9 | 9 | 9 |

5. Discussion

The observational study conducted to assess the safety and performance of four distinct types of sterile surgical gloves has provided comprehensive insights that are critical for both clinical practice and the ongoing development of surgical gloves. The study's findings revealed that powder - free polychloroprene gloves and polymer - coated gloves outperformed orthopaedic gloves and powdered latex surgical gloves in terms of barrier integrity. This result is in line with the research conducted by Rego et al, which emphasized the pivotal role of glove material in maintaining barrier effectiveness against micro - perforations, a common issue that can significantly compromise the sterile field during surgical procedures.^{4,5} The enhanced performance of powder - free polychloroprene and polymer - coated gloves can be attributed to their advanced material composition and manufacturing processes, which seem to provide a more resilient barrier against the rigors of surgical tasks.⁵

In the realm of tactile sensitivity, an essential feature for surgical gloves that ensures precise instrument handling and tactile discrimination, polymer - coated gloves were notably preferred by the study participants. This preference aligns with findings by Palosuo et al, suggesting that the surface treatment of these gloves enhances tactile feedback without undermining their protective function.⁶ The significance of this finding cannot be understated, as surgical procedures often demand high dexterity and fine motor control, particularly in microsurgery and other specialized fields where the ability to feel through the gloves can critically impact surgical precision and, consequently, patient outcomes. The use of single and double glove techniques also contribute to protection and tactile sensation during procedure.⁷ The positive reception of polymer - coated gloves indicates a promising direction for future glove technology, where enhancing tactile sensitivity without compromising safety could lead to significant improvements in surgical performance.^{8 - 10}

However, the study also shed light on a critical concern regarding the incidence of allergic reactions and skin irritation, particularly with the use of orthopaedic gloves.¹¹ This observation echoes the concerns presented by regarding the allergenic potential of certain materials used in surgical

gloves. The adverse reactions noted in the study highlight the importance of not only focusing on the mechanical performance of gloves but also considering their biocompatibility and the potential for causing dermatological issues among healthcare providers. This finding stresses the need for continuous innovation in developing hypoallergenic materials that do not compromise glove safety or performance. It also suggests that healthcare facilities should adopt a more personalized approach to glove selection, taking into account individual sensitivities and allergies, to ensure the well - being of healthcare workers while maintaining the highest standards of patient care.^{11, 12}

These elaborate findings from the study contribute significantly to the existing literature on the efficacy of surgical gloves, providing valuable insights that can guide clinical practices and inform future research and development in this field. The nuanced understanding of how different glove types perform in real - world surgical settings underscores the importance of ongoing evaluation and innovation in surgical glove technology. As advancements continue to be made, such research is indispensable for ensuring that surgical gloves evolve to meet the increasing demands of modern surgical practices, prioritizing both the safety of healthcare workers and the optimal care of patients.

6. Conclusion

In light of these findings, it is evident that the choice of surgical gloves should not only be predicated on barrier protection but also consider factors such as tactile sensitivity, allergenic potential, and user comfort. This study advocates for a multidimensional approach to glove selection, urging healthcare institutions to tailor their choices to the specific needs of their surgical teams and procedures. Future research should continue to explore innovative materials and designs to enhance the performance and safety profiles of surgical gloves, ultimately contributing to improved patient care and healthcare worker safety.

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