

Prevalence of manufacturing defects in latex examination gloves used in selected dental practices in central Saudi Arabia

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ABSTRACT

الأهداف: تقييم مقدار العيوب في قفازات الفحص اللاتكس المستخدمة في عيادات الأسنان المختارة في مدينة الرياض بالمملكة العربية السعودية.

الطريقة: في هذه الدراسة المقطعية، تم جمع 796 من قفازات الفحص اللاتكس من 5 مستشفيات حكومية 5 عيادات الأسنان الخاصة في مدينة الرياض، وقد تم تقييم العيوب الموجودة في القفازات بالفحص البصري وباستخدام اختبار النفخ بالماء. وتم استخدام اختبار تي (t-test) لعينة واحدة وذلك لتقييم الاختلافات في مقدار العيوب بين كل علامة تجارية تم اختبارها وأستخدم أيضا اختبار تي (t-test) لعينتين لتقييم الاختلافات في مقدار العيوب بين المستشفيات الحكومية وعيادات الأسنان الخاصة.

النتائج: أسهم اختبار النفخ بالماء بتحديد العيوب الموجودة في قفازات اللاتكس أكثر من الفحص البصري (20.2% versus 4.3%, p=0.000). باستخدام اختبار النفخ بالماء، كان مقدار العيوب في قفازات اللاتكس ما يقارب بـ 8 أضعاف مستوى الجودة المقبولة (20.2%، p=0.000). وباستخدام اختبار النفخ بالماء، كان معدل العيوب في القفازات المستخدمة في عيادات الأسنان الخاصة أكبر من معدل العيوب في القفازات المستخدمة في عيادات الأسنان الحكومية (25.6% versus 14.6%, p=0.006).

الخاتمة: غالبية قفازات الفحص اللاتكس المستخدمة في عيادات الأسنان الحكومية والخاصة المختارة في الرياض لديها نسبة من العيوب أعلى بكثير من المستويات القياسية المقبولة.

Objective: To assess the defect rates in latex examination gloves used in selected dental practices in Riyadh, Saudi Arabia.

Methods: In this cross-sectional study, a total of 796 latex examination gloves were collected from 5

governmental hospitals and 5 private dental practices between April 2012 and May 2012. The gloves were assessed for presence of defects visually (VT) and using water inflation test (WIT). One and 2 sample t-tests were used to assess significant differences in defect rates among each latex brand, and between governmental hospitals and private dental practices.

Results: Defects in latex gloves were more likely to be identified using WIT compared with VT (20.2% versus 4.3%, p=0.000). Using WIT, examined latex gloves had a defect rate approximately 8 times the acceptable quality level of 2.5% (20.2%, p=0.000). Using WIT, gloves used in private dental practices had significantly higher defect rates compared with governmental dental clinics (25.6% versus 14.6%, p=0.006).

Conclusion: Most latex examination gloves used in the sampled governmental dental clinics and private dental practices in Riyadh had significantly higher preexisting defect rates than acceptable standard levels.

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Cross-infection control should be part of the standard care in every health practice. The standard precautions advocated by the Centers for Disease Control and Prevention aim to reduce the risk of transmission of pathogens from both recognized, and unrecognized infection sources to other patients and health-care workers.¹ Health workers share the same risk factors for infection with hepatitis B virus (HBV), or hepatitis C virus (HCV) as the general public, but their more frequent contact with blood and blood products increases their risk of infection.^{2,3} In addition, health workers who perform invasive procedures, such as surgeons, have generally higher risks for HBV infection.⁴ To minimize chances of cross-infection in medical practices, the Occupational Safety and Health Administration in the United States (OSHA) requires employers to provide, at no cost to the employee, personal protective measures to protect the employee against exposure to blood-borne pathogens.⁵ The reported chance of transmutation of infectious diseases and the recommendations of health organizations has led to a surge in the annual use of latex gloves from one billion to 10 billion between 1987 to 1996.⁶ The possible risk of transmission of pathogenic microorganisms from and/or to patients depends to a great extent on the presence of reliable intact surgical gloves that prevent contact with the patient's bodily fluids. The United States Food and Drug Administration (FDA) requires that the leakage rate of sterile and examination gloves be less than 1.5% and 2.5%.⁷ Checchi and colleagues⁸ indicated that a significant number of perforations were present in unused, non-sterile latex gloves commonly used in dental practices. On the other hand, unused sterile latex surgical gloves have virtually low defect rates.⁹ Compared with other health specialties, latex gloves used in general dentistry and oral surgery practices were found to have higher defect rates.¹⁰ Because of the essential role infection control plays in shaping the dental profession, assessment of the efficacy of gloves used in dental practices in protecting dentists and patients is always viewed as an important issue that deserves continuous evaluation and monitoring. Therefore, this study was undertaken to assess the prevalence of manufacturing defect rates in latex examination gloves used in selected dental practices in Riyadh, Saudi Arabia.

Methods. This cross-sectional study was approved by King Saud University, College of Dentistry Research Center (Registration number: NF2327). For the purpose of this study, 5 governmental dental departments representing 5 commonly visited governmental sector

hospitals were conveniently selected. These dental departments were King Saud University, College of Dentistry (Ministry of Higher Education), King Saud Medical City (Ministry of Health), Riyadh Military Hospital (Ministry of Defense) (now Prince Sultan Military Medical City), King Abdulaziz Medical City (National Guard Health Services), and Security Forces Hospital (Ministry of Interior). Five private dental practices were randomly selected from a list of 228 licensed dental practices obtained from Riyadh Chamber of Commerce and Industry, Riyadh, Saudi Arabia. Two medium-size new latex gloves boxes were collected from each practice between April 2012 and May 2012. Typically these glove boxes contain 100 gloves per box. Forty gloves were selected from each box. In each selection cycle, 5 gloves were taken from each box. From the first box, the first latex glove was assigned to visual testing (VT), and the fifth latex glove was assigned to water inflation testing (WIT). In the second box, the first latex glove was assigned to WIT, while the fifth latex glove was assigned to VT. Each glove was placed in a plastic pouch with an assigned number for glove identification. A total of 796 gloves were assessed for the presence of manufacturing defects. Two examiners unaware of the individual glove assignment assessed the presence of defects using VT and WIT. In cases of disagreement between the 2 examiners in either the VT or WIT observation, a consensus was reached after discussing the presence or absence of a defect. The visual assessment of gloves for any manufacturing defects and/or perforation was performed after wearing gloves by one examiner. Glove defects were visually assessed and classified as defective if a hole and a tear in the glove were observed by naked eye. A water inflation test, which has been recommended by the FDA, was used to detect holes in the gloves.⁷ Briefly, each glove was mounted using Velcro on a 38-cm long plastic tube with a 6-cm outer diameter and 5-cm inner diameter. One thousand milliliters of tap water at room temperature was poured into each glove. Presence of holes in each glove was assessed visually per FDA recommendation immediately and 2 minutes after pouring the water. The defect assessment for manufacturing defects and/or perforation in both VT and WIT was evaluated by 2 examiners. The examiners' reliability in assessing gloves defect rates was performed by comparing the gloves' defect rates in first and second box of same brand.

Statistical analysis. Data were entered and analyzed using the Statistical Package for Social Sciences version 16 (SPSS Inc., Chicago, IL, USA), and was tabulated to assess the presence and frequency of defects in latex gloves. Statistical differences in defects rates for each

latex brand were assessed using one sample t-test set at mean equal to the FDA acceptable quality level (AQL) (2.5%). In addition, statistical differences in defect rates between governmental and private dental practices were assessed using a 2 sample t-test. Statistical differences between VT and WIT in detecting defects were assessed using a proportional 2 sample t-test. Significance level was set at $\alpha=0.05$.

Results. Seven hundred and ninety-six latex gloves drawn from 20 latex gloves boxes were assessed in this investigation. Four gloves were missing, as there were less than 100 gloves in 4 boxes. The defect rates in VT and WIT are presented in Table 1. At both levels of assessment, the defect rates were higher than the required 2.5% AQL for latex examination gloves ($p=0.000$ for WIT). Using VT, there was no significant difference in defect rates in latex gloves between governmental and private practices ($p=0.464$). Using WIT, latex gloves used in private practices had significant higher defect rates compared with governmental practices (25.6% versus 14.6%, $p=0.006$). Table 2 presents the defect rates in the different examined latex gloves brands assessed using WIT. All latex gloves brands except Unimed (Riyadh, Saudi Arabia) had significantly higher defects rate than required 2.5% AQL for latex examination gloves.

Table 1 - Defect rates of latex gloves using visual test and water inflation test.

Method of assessment	n	(%)	P-value
Visual test (N=399)	17	(4.3)	0.000
Water inflation test (N=397)	80	(20.2)	

Discussion. This study was undertaken to determine and compare the defect rates in latex examination gloves used in selected dental practices in Riyadh, Saudi Arabia. Latex examination gloves used in the selected practices have significantly high defect rates. In addition, visual assessment of the latex examination gloves did not adequately identify the high level defects in the gloves assessed in this study.

Dental patients and dental health-care personnel might be at risk of being directly or indirectly exposed to a variety of pathogenic microorganisms.¹¹ Different studies suggest that needle stick injuries in dentistry are not an uncommon problem.^{12,13} Hence, all efforts should be made to reduce the risk of transmission of pathogens from both recognized and unrecognized infection sources to other patients and health-care workers.¹ Therefore, to reduce the chances of cross-infection in health practices, it is expected that infection control measures, such as gloves, are provided by employer at no cost to his/her employees.⁵ The issue of risk of cross-infection at the dental office is always a concern for patients and deserves continuous evaluation and monitoring. Several studies have reported that defects could be present in unused latex gloves.^{14,15} Several techniques have been proposed to assess efficacy of gloves to protect clinicians and patients. Some of these techniques include the electrical conductance test and assessing bacterial penetration through gloves.^{16,17} In addition, more practical methods such as air inflation with water submersion and also WIT have been used to assess defect rates in gloves.^{10,15} The WIT is the method advocated by the FDA, and was used in this study to assess efficacy of gloves in preventing cross-infection.

The assessment of glove defect rates in this study was carried out in 2 phases. In the first phase, approximately

Table 2 - Defect rates for examined latex brands using water inflation test (WIT).

Brand name	Practice No.	Defect rates (WIT)	P-value	Manufacturer (Country)
Medicare	1, 3, 10	25%*	0.000	Unknown (Malaysia)
Unimed	2, 4	3.8%	0.55	Factory of Medical Rubber and Plastic Materials (Saudi Arabia)
Drajeh	5, 6, 7	22%*	0.000	Dar Re'ayat Al-Jazirah (Malaysia)
Al-Jazerah care	8	20%*	0.009	Al-Jazerah Care -Medical Equipments (Malaysia)
Top Gloves	9	32%*	0.000	Top Glove Sdn. Bhd (Malaysia)

*Significantly higher than 2.5% acceptable quality level

half of the examined gloves were assessed visually using the criteria specified by the manufacturers. In the second phase of assessment, the other half of examined latex gloves were evaluated for the presence of defects by using the WIT. These 2 methods were used to correlate clinician visual assessment of glove integrity to a more reliable method such as the WIT. To ensure accuracy in the glove assessment, the 2 examiners in this study were unaware of the brand of glove being examined. In addition, assessment of examiner reliability was evaluated. Ideally, the reliability of each examiner should be performed for the same glove at different time intervals; however, wearing and removing gloves is likely to induce some defects. Therefore, examiner reliability was assessed by comparing the reported defect rate for the same brand in the 2 boxes. It was found in this study that there were no significant differences in the defect rates between latex gloves drawn from the 2 boxes in both WIT and VT.

The findings of this study suggest that there is a variation in the quality of latex examination gloves used in the sampled dental practices. This variation is evident by the fact that the defect rate in one governmental practice was 35%, whereas another governmental practice had defect rate of less than 4%. Most of the defects in this study were not easily detected by visual examination. Several clinical studies suggest that visual detection of perforation is low compared with more reliable methods such as WIT.^{18,19}

Recently, the FDA reduced the AQL for marketing and importing patient examination gloves in the United States from 4% to 2.5% defects within the sampled gloves.⁷ In this study, all latex gloves brands examined exceeded the suggested FDA AQL. In fact, 4 latex gloves brands were at least 8 times the recommended FDA AQL for patient examination gloves. These findings suggest that the majority of latex examination gloves used in sampled dental clinics in Riyadh, Saudi Arabia were disappointingly not meeting the acceptable level to prevent cross-infection in dental practice. In contrast to the high defect rate in the gloves examined in this study, Patel and colleagues¹⁵ found that the preexisting perforation rate in latex examination gloves was 3%. In addition, Kupres and colleagues²⁰ reported that the defect rate of latex examination gloves was 2.3% after routine dermatologic procedures. Hubner and colleagues²¹ found that the defect rate of latex examination gloves was 10.3% after clinical use in intensive care units. This slightly higher perforation rate can be explained by the invasive nature of procedures performed in intensive care units. It is expected from the available evidence on the integrity of latex gloves that the perforation rates of

the sampled gloves would be significantly higher after clinical use. Different factors may increase the risk of perforation of latex gloves. For example, it was found that there was a 3-fold increase in gloves perforation rate after 15 minutes clinical use.²¹ The perforation rate of latex surgical gloves has been also reported to increase with time of use in the clinic.^{22,23} In addition, high perforation rates have been reported for latex surgical gloves in invasive surgical procedures.^{24,25} In many instances, these perforations may not be detected by clinicians and bacterial passage through these perforations could be detected clinically.²⁶ The results of this study showed also that latex examination gloves used in selected private dental practices generally have higher defect rates than those used in governmental dental practices. These higher defect rates in gloves used in private dental practices could be attributed to the perception that private dental practices might be more interested in less expensive gloves that are commonly associated with lower quality.

It was apparent from the results of this study, as well as other studies, that gloves do not provide complete protection from the transmission of infectious diseases. This lack of complete protection is related to some gloves that have defects that may allow leakage of bodily fluids (blood, saliva). Furthermore, some studies have shown that microorganisms can penetrate gloves even if they do not show visible water leaks.¹⁶ In fact, among different health specialties, latex gloves examined after clinical use from general dentists and oral surgeon practices were found to have higher defect rates.¹⁰ This observation would suggest that wearing gloves alone may not be sufficient to protect a dentist from HBV infection. For these reasons, this study reemphasizes on the importance of basic infection control measures such as (1) treating every patient as an infectious patient, (2) vaccination for health-care providers, (3) selection of glove brands that studies show have lower defect rates, (4) checking gloves before and during use, and (5) hand washing before and after treatment between each patient.¹¹ In addition, the findings of this study suggest that the clinicians' assumption that all latex examination gloves present in the market meet the acceptable quality level is not necessarily true. This emphasizes the importance and the urgent need for the regularity bodies in Saudi Arabia, such as the Ministry of Health and the Saudi Food and Drug Authority, to intervene and make sure that the gloves used in the market meet the quality requirements to prevent cross-infection in the health-care practice sector.

This study may have some limitations. Only dental practices in Riyadh were sampled in this study,

which may suggest that results cannot be generalized to all practices in Saudi Arabia. Although this effect is true; however, considering the low quality of latex examination gloves in the capital city of Saudi Arabia, one may expect that the quality of latex examination gloves in different parts of the country may not be better. In addition, the findings of this study could have been more meaningful if assessment of gloves after clinical use had been included. Assessment of gloves after clinical use was not an objective of this study and could be viewed as a potential area of research. Although all efforts were made to make the examiners blind to the latex gloves brand being examined to prevent any bias in the assessment especially the visual assessment; nevertheless, it is expected that the examiners would be able to recognize some brands after examining the same brand several times. This recognition may not affect the assessment of gloves perforation in the visual assessment considering that examiners do not have any preference to specific brands.

In conclusion, the findings of this study indicate that most gloves used in dental departments and practices in the selected sample have significantly higher defect rates than acceptable standard levels. In addition, unsatisfactory performance of patient examination gloves was observed in different dental practices especially in private dental practices. These observations would suggest that acceptable cross-infection standards are not well maintained in most of the examined dental practices in Riyadh, Saudi Arabia.

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