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ORIGINAL ARTICLE

EVALUATION OF SURGICAL GLOVE INTEGRITY: DOES AN AFRICAN COUNTRY RECEIVE INFERIOR QUALITY? EXPERIENCE FROM ADDIS ABABA, ETHIOPIA

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ABSTRACT

Introduction: *In a 2017 study, the incidence of glove perforation in Addis Ababa was found to be much higher than that of most publications—with an incidence of 60.14% for first surgeons. We hypothesized that poor surgical glove quality may have contributed to the high incidence of perforations.*

Method: *We tested the integrity of six widely used brands of sterile surgical gloves that were widely used throughout the nation. The assumption was that the perforation rate in these gloves would be higher than the standard acceptable quality level (AQL) of 1.5, the world standard for surgical gloves at the time of the study.*

Results*: From the 1,200 single gloves evaluated, 59 (4.9%) gloves had perforations and 1,141 (95.1%) did not. Among the brands evaluated, Brand 1 (13.5%) and Brand 5 (10%) had the highest rate of perforations. Compared to the standard AQL of 1.5, Brand 1 and Brand 5 had a significantly higher perforation rate (13.5%, CI=8.8%-18.2%, p=0.000) and (10.0%, CI=5.8%-14.2%, p=0.000), respectively.*

Conclusion*: Our study results showed unacceptably high rates of perforation for 2 glove brands, in which at least 1 out of every 10 gloves were defective. In view of our findings, we recommend, at minimum, that surgeons visually inspect gloves before and after donning. Relevant government institutions, contractors, importers, hospital administrators, and surgical teams must take collective responsibility for ensuring appropriate quality of gloves. Quality enforcement must be strengthened, and local production must be considered.*

Key word: *surgical glove, perforation, brand, quality*

INTRODUCTION

Surgical gloving is a standard sterile practice aimed at protecting the patient and caregivers from transmissible diseases. (1) Perforation of surgical gloves during procedures eliminates this protective barrier and increases the risks to both the patient and the caregiver. (1,2) Patients are two times likely to have a surgical-site infection (SSI) in procedures where gloves are perforated compared to those that maintain aseptic technique.[3] Moreover, as key incidents of patients contracting Hepatitis C virus (HCV) (4) and Hepatitis B Virus (HBV) (5) infections from infected surgeons through glove perforation have been reported in the literature . (6)

Surgical glove perforations may also pose a similar risk to surgical team members, as they may contract transmissible diseases such as Human Immunodeficiency Virus (HIV) (7), HCV (8,9) , and HBV. (3,9,10) One study has reported that surgeons risk more than one HBV infection per lifetime, and at least one in 1500 surgeons are likely to be infected by HIV over the next three decades due to risks posed from surgical glove perforation. (10)

Thus, the integrity of the surgical glove is essential to prevent cross-contamination and decrease the risk of acquired infections to both patients and caregivers alike. There is variability in the literature on the incidence of surgical glove perforations ranging from as low as 10% (6) to as high as 61.7% (11) in some procedures. Factors influencing the variability include type of surgery (12) with emergency surgeries accounting for a significantly higher incidence of glove perforation, (13) duration of surgical procedure with higher incidence of glove perforation in procedures exceeding 90-120 minutes (11), invasiveness of the surgery, experience of the surgeon (1,13) and surgical glove size. (14)

Double gloving is a protective factor which has consistently been shown to reduce the incidence of inner glove perforation. (12,13,15)

In our 2017 study, we found the incidence of glove perforation in Addis Ababa, Ethiopia to be much higher than in other studies with an incidence of 60.14% for first surgeons performing emergency surgery. (13)

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This poses a significant threat to both patients and the surgical workforce. Locally relevant factors that may have contributed to the higher incidence include the standard utilization of surgical residents as first surgeons for emergency procedures, and the limited supply of glove sizes resulting in a portion of the surgical team using inappropriate sized gloves. (13) In addition, because Low and Middle Income Countries (LMICs) like Ethiopia depend on imports, it is possible that poor surgical glove quality may have contributed to the relatively high incidence of surgical glove perforations. It is imperative for relevant stakeholders and policy makers to be aware of the quality of the procured products so they can develop a safer surgical environment for patients and healthcare providers.

We hypothesized that the perforation rate in these gloves would be higher than the standard acceptable quality level (AQL) 1.5, the world standard for surgical gloves at the time of the study. (16,17)

METHODS

Study Procedure:

In this cross-sectional study, 200 powdered size 7.5 latex single gloves from each of the 6 brands of surgical gloves available in pharmacies across Addis Ababa were randomly procured in June 2018. Each of the gloves studied here were manufactured by different companies, and in different countries. A total of 1,200 single gloves were examined. The characteristics of each brand of surgical glove including origin, constituent materials, cost, method of sterilization, quality assurance measures, available sizes, glove thickness, tensile thickness, elongation measures and storage recommendations were identified (Table 5). Since Ethiopia did not produce surgical gloves at the time of the study, local products were not included in the study.

Control testing for surgical glove integrity was conducted for each glove using a standardized visual and a European Norm (EN) 455-1 water-leak test method.[17,18] The tests were carried out by two individuals who were blinded to the surgical glove brand. The visual test assessed for overt damage by inspection. For the water-leak test, each glove was filled with 1L of water and methylene blue solution at room temperature followed by manual compression on the wrist of the glove for 1 minute. Leakage of blue water indicated perforation. The number and locations of the perforations were recorded for each glove.

Statistical Analysis

Descriptive statistics were computed for the categorical variables. A proportion t-test was utilized to test for difference in proportions between each brand and the null hypothesis of 0.04.

The null hypothesis was derived from what the acceptable maximum is (8 defects) for an AQL of 1.5 in an n=200 random sample. (17) A difference in proportions using proportion t-test was also conducted for: (1) the total right versus total left hand gloves perforated in the total sample, (2) perforation in the right versus left gloves among each of the 6 brands, (3) the total perforation in the palmar versus dorsal aspects in the total sample size, and (4) the perforation in the palm versus dorsum versus both sides among each of the 6 brands. A Pearson chi-square analysis was conducted to determine an association between the glove digits and the outcome, perforation. All p-values were two-sided with a statistical significance level of $p<0.05$. All statistical analyses were conducted using Stata (version 14.2, Stata Corp, College Station, Texas, USA).

RESULTS

From the 1,200 single gloves evaluated, 59 (4.9%) gloves had perforations and 1,141 (95.1%) did not. Among the brands evaluated, Brand 1 (13.5%) and Brand 5 (10%) had the highest rate of perforations, followed by Brand 3 (3.0%) Brand 6 (2.0%), Brand 2 (1.0%) and Brand 4 (0%) (Table 1). Compared to the standard AQL 1.5 for surgical gloves at the time of the study,[16,17] Brand 1 and Brand 5 had significantly higher perforation rate (13.5%, CI=8.8%-18.2%, p=0.000) and (10.0%, CI=5.8%-14.2%, p=0.000), respectively. There was no significant difference between the AQL and perforation rates for Brand 2 (2.0%, CI=-0.4%-2.4%, p=0.985), Brand 3 (3.0%, CI=0.6%-5.4%), p=0.985), Brand 4 (0.0%, CI=0.0%-0.0%, p=0.998) and Brand 6 (2.0%, CI=0.1%-3.9%, p=0.926) (Table 1).

Among the 600 right and 600 left hand gloves evaluated, there were a total of 35 (5.8%) right hand glove perforations and 24 (4.0%) left hand glove perforations. There was no statistically significant difference between total right (5.8%, CI=3.9%-7.7%) and total left hand (4.0%, CI=2.4%-5.6%) glove perforation rates (p=0.149) (Table 2). The right-hand perforation rate (16.0%, CI=8.8%-23.2%) was significantly higher than the left-hand perforation rate (4.0%, CI=0.2%-7.8%) in Brand 5 (p=0.005) (Table 2). The left-hand perforation rate (4.0%, CI=0.2%-7.8%) was significantly higher than the right-hand perforation rate (0.0%, CI=0.0% -0.0%) in Brand 6 (p=0.043).

There was no significant difference in the right and left glove perforation rates in Brand 1 (13.0% vs. 14.0%, p=0.836), Brand 2 (2.0% vs. 0.0%, p=0.155), and Brand 3 (4.0% vs. 2.0%, p=0.407). The p-value was not computed for Brand 4, which had 0 perforations (Table 2).

Table 1: Differences in perforation rate of surgical brands compared to the standard AQL

	Non-Perforated (n=200)	Perforated (n=200)	95% CI	p-value (Ha: p > 0.04)
Brands, n (%)				
Brand 1	173.0 (86.5%)	27.0 (13.5%)	8.8% - 18.2%	0.000
Brand 2	198.0 (99.0%)	2.0 (1.0%)	-0.4% - 2.4%	0.985
Brand 3	194.0 (97.0%	6.0 (3.0%)	0.6% - 5.4%	0.765
Brand 4	200.0 (100.0%)	0.0 (0.0%)	0.0% - 0.0%	0.998
Brand 5	180.0 (90.0%)	20.0 (10.0%)	5.8% - 14.2%	0.000
Brand 6	196.0 (98.0%)	4.0 (2.0%)	0.1% - 3.9%	0.926

CI= Confidence Interval; Ha=Null hypothesis

Table 2. Differences in glove perforation rate between right and left hands

	Right Hand (n=100)	95% CI	Left Hand (n=100)	95% CI, (%)	p-value
Brands, n (%)					
Brand 1	13.0 (13.0%)	6.4%-19.6%	14.0 (14.0%)	7.2%-20.8%	0.836
Brand 2	2.0 (2.0%)	-0.7%-4.7%	0.0 (0.0%)	0.0%-0.0%	0.155
Brand 3	4.0 (4.0%)	0.2%-7.8%	2.0 (2.0%)	-0.7%-4.7%	0.407
Brand 4	0.0 (0.0%)	0.0%-0.0%	0.0 (0.0%)	0.0%- 0.0%	N/A
Brand 5	16.0 (16.0%)	8.8%-23.2%	4.0 (4.0%)	0.2%-7.8%	0.005
Brand 6	0.0 (0.0%)	0.0%-0.0%	4.0 (4.0%)	0.2%-7.8%	0.043
Total, n (%) (n=600)	35.0 (5.8%)	3.9%-7.7%	24.0 (4.0%)	2.4%-5.6%	0.149

CI=Confidence Interval

Of the total 1200 gloves perforated, the palmar side was perforated at a significantly higher rate (4.5%, CI=3.3%-5.7%) than the dorsal side (0.5%, CI=0.1% -0.9%) (p=0.001). Among the brands evaluated, the palmar side was perforated at a significantly higher rate than the dorsal side in Brand 1 (12.0% vs. 0.2%, p=0.001), Brand 3 (3.0% vs. 0.0%, p=0.014) and Brand 5 (10.0% vs. 0.0%, p=0.001).

There was no significant difference in the perforation rates between the palmar and dorsal side in Brand 2 (1.0% vs. 0.0%, p=0.156) and Brand 6 (1.0% vs. 1.0%, p=1.000). The p-value was not computed for Brand 4, which had 0 perforations (Table 3).

Of the total perforated gloves with single digit perforations, the highest rates of perforations were found in Digit 1 (Thumb) (39.6%), followed by Digit 3 (Middle) and Digit 5 (Little) (17.0%), Digit 2 (Index) (15.1%), and Digit 4 (Ring) (11.3%). There was a statistically significant difference in the rates of perforation among the 5 digits evaluated (p=0.009).

Brand 5 had the highest rate of perforations for Digit 1 (71.4%) and Digit 5 (55.6%), Brand 1 for Digit 2 (75.0%) and Digit 3 (55.6%) and Digit 4 (100.0%) (Table 4). Only digit perforations that were independent were included in the analysis and six perforated gloves which had perforations in more than 1 digit were excluded from the digit specific analysis.

Table 3: Differences in glove perforation rate between palmar and dorsal aspects

	Palmar Aspect (n=200)	**95% CI**	**Dorsal Aspect (n=200)**	**95% CI**	**p-value**
Brands, n (%)					
Brand 1	24.0 (12%)	7.5%-16.5%	4.0 (0.2%)	0.1%-3.9%	0.001
Brand 2	2.0 (1.0%)	-0.4%-2.4%	0.0 (0.0%)	0.0%-0.0%	0.156
Brand 3	6.0 (3.0%)	0.6%-5.4%	0.0 (0.0%)	0.0%-0.0%	0.014
Brand 4	0.0 (0.0%)	0.0%-0.0%	0.0 (0.0%)	0.0%-0.0%	N/A
Brand 5	20.0 (10.0%)	5.8%-14.2%	0.0 (0.0%)	0.0%-0.0%	0.001
Brand 6	2 (1.0%)	-0.4%-2.4%	2 (1.0%)	-0.4%-2.4%	1.000
Total, n (%) (n=1200)	54 (4.5%)	3.3%-5.7%	6 (0.5%)	0.1%-0.9%	0.001

CI=Confidence Interval

Table 4: Differences in glove perforation rate by digit among the six brands

	Total Non-Perforated (n = 5947)	**Total Perforated (n = 53)***	**p-value**
Digits, n (%)			
Digit 1 (Thumb)	¨1179 (19.8%)	¨21.0 (39.6%)	
~Brand 1	198.0 (16.8%)	2.0 (9.5%)	
Brand 2	198.0 (16.8%)	2.0 (9.5%)	
Brand 3	198.0 (16.8%)	2.0 (9.5%)	
Brand 4	200.0 (17.0%)	0.0 (0.0%)	
Brand 5	185.0 (15.7%)	15.0 (71.4%)	
Brand 6	200.0 (17.0%)	0.0 (0.0%)	
Digit 2 (Index)	¨1192 (20.0%)	¨8.0 (15.1%)	
~Brand 1	194.0 (16.3%)	6.0 (75.0%)	
Brand 2	200.0 (16.8%)	0.0 (0.0%)	^0.009
Brand 3	198.0 (16.6%)	2.0 (25.0%)	
Brand 4	200.0 (16.8%)	0.0 (0.0%)	
Brand 5	200.0 (16.8%)	0.0 (0.0%)	
Brand 6	200.0 (16.8%)	0.0 (0.0%)	
Digit 3 (Middle)	¨1191 (20.0%)	¨9.0 (17.0%)	
~Brand 1	195.0 (16.4%)	5.0 (55.6%)	
Brand 2	200.0 (16.8%)	0.0 (0.0%)	
Brand 3	198.0 (16.6%)	2.0 (22.2%)	
Brand 4	200.0 (16.8%)	0.0 (0.0%)	
Brand 5	200.0 (16.8%)	0.0 (0.0%)	
Brand 6	198.0 (16.6%)	2.0 (22.2%)	
Digit 4 (Ring)	¨1194 (20.1%)	¨6.0 (11.3%)	
~Brand 1	194.0 (16.2%)	6.0 (100.0%)	
Brand 2	200.0 (16.8%)	0.0 (0.0%)	
Brand 3	200.0 (16.8%)	0.0 (0.0%)	
Brand 4	200.0 (16.8%)	0.0 (0.0%)	
Brand 5	200.0 (16.8%)	0.0 (0.0%)	
Brand 6	200.0 (16.8%)	0.0 (0.0%)	
Digit 5 (Little)	¨1191 (20.0%)	¨9.0 (17.0%)	
~Brand 1	196.0 (16.5%)	4.0 (44.4%)	
Brand 2	200.0 (16.8%)	0.0 (0.0%)	
Brand 3	200.0 (16.8%)	0.0 (0.0%)	
Brand 4	200.0 (16.8%)	0.0 (0.0%)	
Brand 5	195.0 (16.4%)	5.0 (55.6%)	
Brand 6	200.0 (16.8%)	0.0 (0.0%)	

CI=Confidence Interval
** = Data includes only independent surgical glove perforations, excludes 6 surgical gloves that had perforations in more than 1 digit*
^ = p-value from the Pearson Chi Square analysis of association of rate of total perforations between the 5 digits
~ = Descriptive analysis of the total number of digits perforated and nonperforated in each where n =¨,the total number of perforations and non-perforations for each Digit

DISCUSSION

It is imperative to investigate underlying reasons for high post-operative glove perforation rates in the Ethiopian surgical space, as previous research has shown rates as high as 38.3% overall, and 60.14% in primary surgeons during emergency surgery. (13) These rates are higher than those from most other LMICs, (12,19) and intra-operative events may be insufficient to explain these findings. Pre-operative testing in our study revealed an overall perforation rate of 4.9% and peak brand perforation rates of 13.5% (Brand 1) and 10% (Brand 5) prior to glove use.

This constitutes a surgical safety hazard and represents a significant deviation from acceptable industry standards at the time of study of less than 8 defective gloves in 200 (AQL of 1.5). (17) Our findings sharply contrasts those by Hwang *et al,* from a Taiwan high income setting, in which pre-operative testing of 198 gloves from 4 manufacturers revealed a 0% perforation rate. (20) Green and Gompertz in the United Kingdom demonstrated 2%. (1) Albin *et al* demonstrated a defect rate in the United States of 1.9% before dental procedures and 5.5% before surgical procedures. (21) In 1989, just prior to the introduction of new and stringent regulations to the United States, similar rates to our findings (3-16%) were found on surgical glove testing by visualization and water fill by the US Food and Drug Administration. (22) As lower rates of pre-use perforations represent a proxy for increasing quality, this study raises significant quality questions for gloves in circulation within the country.

The brands with highest perforation rates in our study had significantly higher rates of perforation relative to other brands. On the lower end of the spectrum, Brand 4 gloves had no pre-use perforations. These results suggest that rates of glove perforation vary significantly with glove brand and manufacturer. Even though lot to lot variability within brands may exist, this quality variability reveals a standardization challenge in the Ethiopian surgical safety and medical importation regulatory space which needs to be addressed at governmental and institutional levels. Ethiopia can contextualize some HIC federal regulations which require random inspection of gloves using the Water Load Test. (16)

All gloves tested in this study were imported. The number of gloves imported into Ethiopia has steadily increased over the years, with an annual growth in quantity of imports of 137% per annum between 2015 and 2019. (23)

At around the time of the study, Ethiopia's import ranking for surgical gloves was 34th in the world, representing 0.5% of world imports for gloves. (23) The imported value of surgical gloves into the country in 2019 alone was US $10,457,000. (23) In Ethiopia, surgical gloves have a limited number of supplying markets, led by China, followed by India, Malaysia, Austria, the United Kingdom, Belgium and Germany. (23) Brands represented in this study reflected the bulk of the supplying market. Investing in the importation of gloves that are shown to have a lower rate of perforation prior to use is a potential solution to low quality market brands, but, better still, local production of surgical gloves to regulatory standards may represent a more feasible solution. It can be argued that these defective glove brands portend danger on the basis of handedness, surface and digits of perforation. Our findings with regards to the handedness of the perforations suggest no statistically significant differences overall (p=0.149), however in one of the precarious brands, right-handed perforations were significantly higher than left-handed perforations (p=0.005). Handedness of Ethiopian surgical staff has not yet been explored, but a wider review suggests that majority of surgeons are right-handed. (24)

Although the "holding" or non-dominant hand is at risk of intra-operative perforations (owing to a lower degree of dexterity and greater exposure to needle puncture), (12,13,20,21,25,26) our findings may suggest a subtle increase in danger to the patient and surgeon, as right handed surgeons who utilize these defective gloves on their dominant hands additionally have a higher risk of intra-operative perforations on their non-dominant hands. With regards to perforated glove surfaces, the palmar aspect was perforated at a significantly higher rate (4.5%, CI=3.3%-5.7%) than the dorsal aspect (0.5%, CI=0.1%-0.9%)(p=0.001) overall. This finding was also specific to the most perforated brands (1 and 5). Palmar perforations arguably portend a greater danger than dorsal perforations with regards to the major surface of surgical contact. These pervasive perforations involved all digits, however, of the total single digit perforations, the highest rates of perforation were found on the thumb (39.6%). The thumb is the most important digit for grasping and fine surgical hand motions. The non-dominant thumb in combination with the non-dominant index finger have been established by research consensus as the most common sites of intra-operative glove perforation. (12,13,20,21,25,26) This trifecta of handedness, surface and digit elevates the danger of utilizing the defective brands.

In view of our findings of a large proportion of glove perforations prior to use, we recommend, at minimum, that surgeons visually inspect gloves before and after donning. The use of a double glove perforation indicator system may serve as an early warning system for pre-perforated gloves. For Ethiopian surgical teams who do not routinely use double glove for resource constraint reasons, results of our study strongly suggest right-sided double-gloving to mitigate risks associated with the demonstrated laterality of these pre-existing perforations. Widespread testing and Hepatitis B vaccination of surgical staff should still be encouraged, and Ethiopian authorities should intervene to protect surgeons and patients, to maximize investments in the surgical sector, and to drive down surgical site infections which now stand at a pooled prevalence of 12.2%. (27)

More importantly, possible facilitators of the entry of low-quality gloves into Ethiopia, like loose legislation, irregular public procurement, and substandard quality control need to be creatively addressed. Brands not meeting up to standards should be banned from the Ethiopian space and high-quality brands should be rewarded. Brand 4 has demonstrated that conforming to quality standards are possible, as is often the case in strictly controlled HIC environments. (20) All health systems are vulnerable to corruption. (28) Ethiopia seems to be taking corruption in the health sector seriously, however, some authors have referenced poorly functioning reporting systems around hospital procurement and distribution processes. (28)

Officials must ensure that there is no interference with the set standards for glove approval, compliance certification, and licensing. The present findings could also serve as a call to strengthen transparency and accountability and increase performance measurement, monitoring, and enforcement in existing quality enforcement agencies.

Limitations of this study include our inability to test all glove brands and all sizes in use. However, we assessed the brands and size most commonly used during operations in Ethiopia. Furthermore, despite the fact that this study assessed for perforations using the standard methods utilized by quality control agencies, some studies suggest that newer testing methods like electrical conductance tests, may have revealed higher perforation rates (29). Furthermore, the contribution of additional characteristics (including thickness and elasticity) of the gloves to perforation rates was not measured. Finally, following conclusion of this study, progress has been made by international regulators to raise quality standards for surgical gloves by reducing the AQL to 0.65. (18) Further studies should be carried out in Ethiopia to determine conformity to this new benchmark. (18)

Conclusion

Various brands of gloves manufactured in different countries are routinely imported for surgical procedures in Ethiopia, with high variability in quality between brands. Our study results show unacceptably high rates of perforation for 2 glove brands, in which at least 1 out of every 10 gloves were defective.

The implications of this are staggering for surgical staff. In Ethiopia, choice of surgical glove brand may be a determinant of surgical safety. These findings also indicate that unrecognized pre-operative perforations may be a contributing factor to the high post-operative glove perforations identified in our previous study. Further studies are needed to understand how the intrinsic characteristics of gloves contribute to these rates of perforation. Relevant government institutions, contractors, importers, hospital administrators, and surgical teams must take collective responsibility for ensuring appropriate quality of gloves. Quality enforcement must be strengthened, and local production must be considered.

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Conflicts of interest

The authors report no conflicts of interest, financial or otherwise.

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