

What Role Does a Colored Under Glove Have in Detecting Glove Perforation in Foot and Ankle Procedures?

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Abstract

Background Many orthopaedic surgical teams practice double gloving or use colored indicator gloving techniques to reduce contamination intraoperatively. Although the likelihood of glove perforation can be affected by the procedure type and surgeon habits, as well as the surgeon's technique, these factors have not been considered to determine the glove perforation rate, and the role of a colored under glove during operations seems less investigated.


Questions/purposes (1) What proportion of foot and ankle procedures result in perforation of outer gloves or under gloves? (2) What factors (such as the type or duration of operation) appear to be associated with the likelihood of

glove perforation? (3) Does the use of a colored indicator under glove make it more likely that a surgeon would perceive the perforation of an outer glove intraoperatively?

Methods Between September 2020 and August 2021, the author performed 577 surgical foot or ankle procedures. Of those, patients who underwent subsequent operations under general or spinal anesthesia were considered as potentially eligible. Further, 16% (93) were excluded because the procedures were performed with the patient under local anesthesia, and another 1% (eight patients) were not analyzed (incomplete datasets for emergency operations performed at night). Finally, 82% (476 patients) were examined. To ensure statistical independence, gloves used in right-side operations in bilateral procedures and the most proximal surgery in unilateral procedures were included. Preoperatively, the surgeon was randomly assigned to use either a combination of two regular surgical gloves or a regular outer glove worn over a colored indicator under glove. Patient diagnosis, type of procedure, tourniquet time, and gloving type were recorded. There was no difference in potentially relevant confounding variables, such as the proportion of procedures performed on bone (78% [188 of 242] versus 83% [195 of 234]; $p = 0.13$), nor in tourniquet time (58 ± 30 minutes versus 62 ± 31 minutes; $p = 0.45$) between the regular glove and indicator glove groups. At the end of each procedure, the surgeon was asked whether he believed either the outer or under glove was perforated, and whether the use of a colored under glove increased the proportion of procedures in which the surgeon correctly ascertained that a perforation had occurred. To determine the proportion of gloves that were perforated, a standardized water-leak method was used, and the proportion of gloves with perforations based on several parameters of interest, including bone versus soft tissue operation and tourniquet time, was compared.

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Results During 476 foot and ankle procedures, the overall glove perforation proportion was 19% (92 of 476 procedures). Under-glove perforation was observed in 4% (17 of 476 procedures) of the operations. There was no difference in glove perforation proportions between bone and soft tissue operations (76 of 383 versus 16 of 93; odds ratio [OR] = 0.84, 95% confidence interval [CI] 0.46 to 1.52; $p = 0.56$). As tourniquet time (operation time) increased, the glove perforation proportion also increased (Exp[B] = 1.02; 95% CI 1.01 to 1.03; $p < 0.001$). The use of indicator under gloves increased the surgeon's intraoperative detection of glove perforation (in 68% of procedures [32 of 47] versus 29% [13 of 45]; OR = 5.3; 95% CI 2.2 to 12.8; $p < 0.001$).

Conclusion Surgical glove perforation occurred in approximately one of five foot and ankle procedures. Based on the results of this study, I recommend using colored indicator under gloves and replacing the under glove when replacing the outer glove after perforation is seen in order to detect contamination early and reduce any intraoperative contamination related to glove injury.

Level of Evidence Level I, therapeutic study.

Introduction

In 1889, Caroline Hampton was the first scrub nurse to use a surgical glove to protect her hands from dermatitis [18]. Since then, surgical gloves have been widely used in the medical field. Surgical gloves protect the surgical team and patients from perioperative infection. To do this, gloves must remain intact intraoperatively.

The integrity of surgical gloves can be affected by the type of surgical procedure, duration of wear, and the staff member's role on the surgical team [1, 9]. Several types of gloves and gloving techniques, including thick latex surgical gloves, stainless steel gloves, double latex gloves, and colored gloves, are available to protect patients and staff from transmissible disease and the patient from acquiring a surgical site infection [7, 8]. In orthopaedic operations, the risk of glove perforation may be increased because sharp instruments, such as pins and wires, are frequently used for these procedures, and sharp, bony edges are common [10]. The proportion of gloves that are perforated intraoperatively has been reported to vary between 12% and 52% [10, 12, 13, 16]. Several studies have shown the effectiveness of the double-gloving technique [4, 7, 19], and many orthopaedic surgical teams use it.

Because intraoperative glove perforation is so common, despite double gloving, some surgeons use colored indicator under gloves for the early detection of outer glove perforation. A previous study showed that using an indicator glove can decrease the proportion of perforation of the under glove in orthopaedic trauma procedures [10].

However, previous studies regarding glove perforation reported results with a mix of procedures or multiple surgeons [2, 4, 7, 8, 10, 19]. Because glove perforation proportions can be affected by the procedure type, surgeon technique and habits, and differences in the likelihood that different surgeons might detect perforation, it seems important to perform a study designed to control for those variables.

In this study, I asked: (1) What proportion of foot and ankle procedures result in perforation of outer gloves or under gloves? (2) What factors (such as the type or duration of operation) appear to be associated with the likelihood of glove perforation? (3) Does the use of a colored indicator under glove make it more likely that a surgeon would perceive the perforation of an outer glove intraoperatively?

Materials and Methods

Study Design and Setting

This was a prospective, single-center, single-surgeon (SYL) comparative trial. In it, all gloves used in foot and ankle operations performed by the author between September 2020 and August 2021 were examined. The author is right-handed and subspecialty-trained, and has 16 years of orthopaedic experience.

Participants

Between September 2020 and August 2021, the author performed 577 surgical foot or ankle procedures. Of these, patients who underwent subsequent operations under general or spinal anesthesia were considered as potentially eligible. Further, 16% (93) were excluded because the procedures were performed with the patient under local anesthesia, and another 1% (eight patients) were not analyzed (incomplete datasets from emergency operations performed at night). Finally, 82% (476 patients) were examined. To ensure statistical independence, gloves used in right-side operations in bilateral procedures and the most proximal surgery in unilateral procedures were included.

Patients' Baseline Data

There was no difference was in potentially confounding variables such as the proportion of procedures performed on bone (78% [188 of 242] versus 83% [195 of 234]; $p = 0.13$) nor in tourniquet time (58 ± 30 minutes versus 62 ± 31 minutes; $p = 0.45$) between the regular glove and indicator glove groups (Table 1).

Table 1. Comparison of clinical data between the two groups

Parameter	Regular glove group	Indicator glove group	p value
Type of procedure, % (n)			
Bone/soft tissue	78 (188/242)	83 (195/234)	0.13
Bone operation, % (n)			
Trauma/non-trauma	78 (146/188)	77 (150/195)	0.86
Trauma operation, % (n)			
ORIF/CRIF	91 (133/146)	1 (136/150)	0.90
Tourniquet time in minutes, mean ± SD	58 ± 30	62 ± 31	0.45

ORIF = open reduction and internal fixation; CRIF = closed reduction and internal fixation.

Interventions

Before each operation, the author was assigned to use either a combination of two regular surgical gloves or colored indicator under gloves. The types of gloving were randomized in a 1:1 ratio by an advanced-practice nurse through a preset, computer-generated, random table.

An Ansell Gammex[®] powder-free latex glove (Ansell) was used for the regular surgical glove (size 8 for the outer glove and size 7 1/2 for the under glove). Intraoperatively, the surgeon used a size 7 1/2 PROTEXIS[®] Latex Blue with Neu-Thera[®] (Cardinal Health) glove for the colored indicator under glove.

If glove perforation was noted intraoperatively, the glove was replaced with the same type of glove, and this was recorded as glove perforation. To avoid duplicate data, glove perforation that occurred after glove replacement was not recorded. There was no regular, focused inspection stage intraoperatively. Intraoperative glove perforation was noticed incidentally. For the same reason, subglove perforation was not categorized as noted perforation because subglove perforation is generally found through close inspection by a surgeon while replacing the outer glove during the operation.

After each procedure, each of the outer and under gloves was tested for perforations using the approved standardized water-leak test method, EN455 Part 1 [6]. The glove, which was attached to a filling tube, was filled with 1000 ml ± 50 ml of water at 15°C to 35°C to assess glove perforation. Because a consistent investigator who could participate in all the operations for 1 year was needed, the surgeon and advanced-practice nurse, who were not blinded, inspected the glove visually for water leakage immediately and 2 minutes after the glove was filled with water (Fig. 1). If even one investigator identified a water leak, it was recorded as a glove perforation.

Potential factors affecting glove perforation were diagnosis, type of procedure, tourniquet time, and gloving

type. The actual operation time was replaced by tourniquet time. Because the tourniquet time was accurately recorded in the medical record, using the tourniquet time was thought to be consistent and reflect the actual operation time.

A total of 476 foot and ankle operations were included in the final analysis. Regular double gloving was used in 51% (242) of the procedures, while colored indicator under gloves were used in 49% (234). Eighty percent of the operations (383) were categorized as bone operations, including treatment for bony deformity, arthritis, and fracture, and 20% (93) were categorized as soft tissue operations, including ankle instability, arthroscopy, soft tissue trauma, and diabetic foot. The mean tourniquet time was 60 minutes ± 31 minutes (range 7-160 minutes).

Primary and Secondary Study Outcomes

The primary goal was to assess the proportion of foot and ankle procedures resulting in perforation of outer gloves or under gloves. To achieve this, the surgeon was asked whether he believed either the outer or under gloves were perforated and ascertained whether the use of a colored under glove increased the proportion of procedures in which the surgeon correctly ascertained that a perforation had occurred. To determine the proportion of gloves that were perforated, the standardized water-leak method was used.

The secondary goals were to evaluate factors potentially affecting glove perforation and to investigate the effect of using a colored indicator under glove to perceive the perforation of an outer glove intraoperatively. The percentage of gloves with perforations was compared based on several parameters of interest, including bone versus soft tissue operations and tourniquet time. The type of gloving was allocated in a 1:1 ratio preoperatively.

Ethical Approval

This prospective study was reviewed and approved by the institutional review board of my institution (number 2020-09-021). The study was exempted from full-scale review because the study did not pose greater than minimal risk and did not involve research participants.

Statistical Analysis

Descriptive statistics were used to summarize the patients' demographic and radiographic data. A chi-square test was used to compare categorical data between the two groups.

A binary logistic regression analysis was used to identify whether the surgical time (tourniquet time) was associated with the percentage of procedures in which glove perforation was noted. All statistical analyses were conducted with SPSS version 20.0 (IBM Corp), and p values < 0.05 were considered significant.

Results

Proportion of Procedures With Glove Perforation

The overall proportion of intraoperative glove perforation, regardless of the number of glove perforations during the same operation, was 19% (92 of 476 procedures). Overall, 69% (63 of 92) of perforated gloves were on the left side and 16% (15 of 92) were on the right side. Bilateral glove perforation was reported in 15% of perforated gloves (14 of 92) (Fig. 2). Under-glove perforation was observed in 4% (17 of 476) of operations. Under gloves were perforated on the left side in seven of 17 and on the right in five of 17. Bilateral under-glove perforation was also found in five of 17 under-glove perforations.

Factors Associated With Glove Perforation

Increased tourniquet time was associated with a greater likelihood of glove perforation (Exp[B] = 1.02; 95% confidence interval [CI] 1.01 to 1.03; $p < 0.001$). There was no difference in the glove perforation proportion between bone and soft tissue operations (76 of 383 versus 16 of 93; odds ratio [OR] 0.84; 95% CI 0.46 to 1.52; $p = 0.56$). The glove on the left side was perforated in a greater percentage of procedures than the glove on the right side (16% [77 of 476] versus 6% [29 of 476]; 95% CI 2.6% to 12.4%; $p < 0.001$).

Did Colored Indicator Gloves Increase the Detection of Glove Perforation?

Glove perforation was detected in a greater percentage of procedures in which colored indicator under gloves were used than those in which they were not used (68% [32 of 47] versus 29% [13 of 45]; OR 5.3; 95% CI 2.2 to 12.8; $p < 0.001$) (Table 2). However, wearing colored indicator under gloves intraoperatively did not decrease the proportion of under gloves that were perforated (17% [eight of 47]

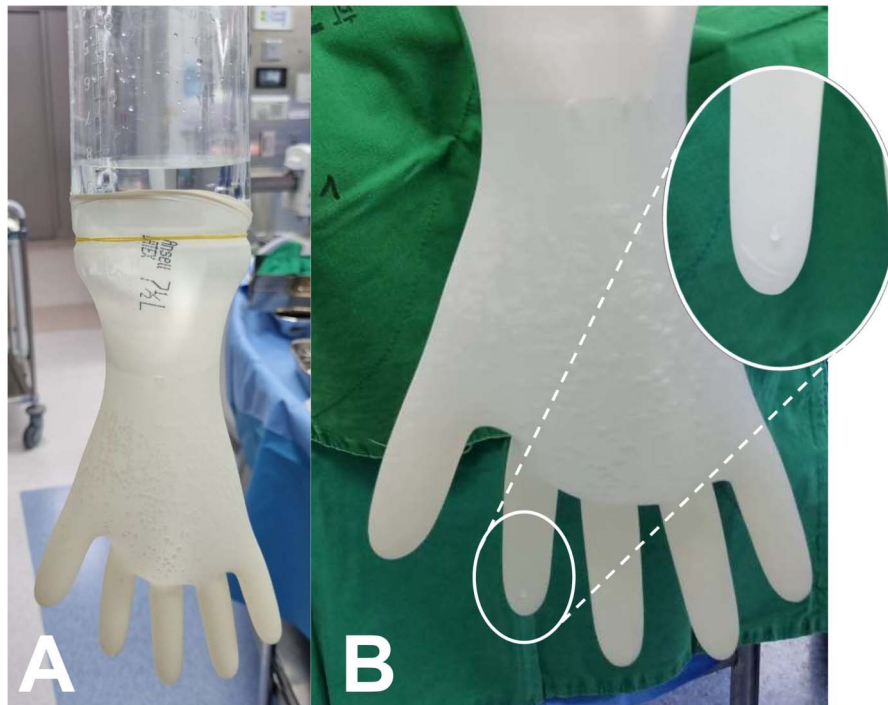


Fig. 1. As shown in these photographs, (A) after each procedure, the outer and under gloves were tested for perforation using a water-leak test. According to the protocol of EN455 Part 1 [6], 1 L of normal saline at room temperature was put in the glove using a tube. (B) In the experimental situation, water leakage could be identified (in the white circle) through a perforation made with a 26-gauge needle.

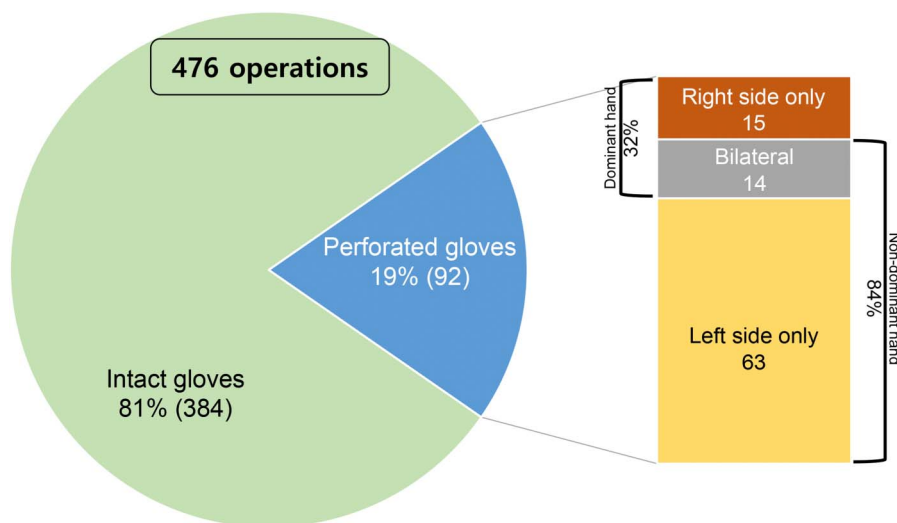


Fig. 2. This pie chart represents the outer glove perforation proportion and laterality.

versus 20% [nine of 45]; OR 0.8; 95% CI 0.3 to 2.4]; p = 0.71).

Discussion

Surgical gloves must remain intact intraoperatively so they are the most effective. Although the likelihood of glove perforation can be affected by procedure type and surgeon habits as well as the surgeon’s technique, few studies I know of have considered multiple factors affecting glove perforation. I assessed the overall glove perforation proportion and effectiveness of a colored indicator under glove during foot and ankle operations I performed. In this study, the outer glove was damaged in one of five foot and ankle procedures. The proportion of outer glove perforation was affected by the operation time, regardless of the operation type. The use of indicator gloves increased the detection of glove perforation intraoperatively; however, it did not decrease the under-glove perforation proportion. To reduce unrecognized glove perforation intraoperatively, surgeons

might use colored under gloves and should pay more attention to glove perforation in long procedures. I recommend using colored indicator under gloves and replacing the under glove when replacing the outer glove after perforation to reduce contamination related to glove injury.

Limitations

This study has limitations. First, this is not a blinded study; therefore, there might be an assessment bias. It was hard to blind the type of gloves when wearing them. Although it was difficult for me to closely examine the gloves intraoperatively because I was focused on the procedure, I might have unconsciously observed them more closely when I wore certain gloves intraoperatively. For interpreting the water-leak test without blinding, I thought it was important to include consistent investigators who could participate in all operations for 1 year. Two investigators evaluated the test results simultaneously to reduce bias when interpreting the test. Second, the number of

Table 2. Glove perforation proportion according to the glove type in foot and ankle procedures

Parameter	Double glove ^a (n = 242)	Colored glove ^b (n = 234)	Odds ratio (95% CI)	p value
Under glove ^c	4% (9)	3% (8)	0.8 (0.3-2.4)	0.71
Outer glove				
Perforation ^d	19% (45)	20% (47)	1.1 (0.7-1.7)	0.17
Noted perforation ^e	5% (13)	14% (32)	5.3 (2.2-12.8)	< 0.001

^aRegular double-glove group.

^bColored indicator under-glove group.

^cUnder-glove perforation in each group.

^dIntraoperative glove perforation regardless of recognition.

^eGlove perforation noted intraoperatively.

under-glove perforations was too small to interpret the results. My study did not prove that wearing an indicator under glove can reduce under-glove perforation. However, I could not examine the under glove during the operation. Therefore, my decision to use colored indicator under gloves and replace the under glove when replacing the outer glove after perforation would not be affected by the number of under-glove perforations. Third, a microbial study was not conducted. The clinical infection rate is beyond the scope of the present study. For the clinical infection rate, studies should be conducted with a different design to consider various other factors. Although glove perforation can be associated with clinical infection, to my knowledge, few studies have examined procedures in which glove perforation is detected intraoperatively. Therefore, I propose replacing all gloves, including the under glove, to reduce glove perforation. I understand there might be a concern of contamination during replacement of all gloves; however, changing gloves can be done sterilely and should be done away from the surgical field, and the cost of the extra gloves seems small relative to the risk of operating with a perforated glove. Replacing all gloves seems better than pushing ahead with the risk that the under glove was perforated. Fourth, this study was conducted assuming there were no glove defects. Because the integrity of the gloves was not evaluated before use, gloves with defects might have been included in this study. However, manufacturers inspect gloves after production; therefore, the defect rate can be very low. There was no subglove perforation in intact outer gloves after the operation. Moreover, I tried a water-leak test on 31 pairs of new gloves but could not find a defect. Therefore, I believe that the impact of the defect rate on these study results would be limited. Fifth, there is a concern regarding tourniquet time, which replaced operation time in the present study. For consistency of data, I used tourniquet time as a substitute for operation time. Tourniquet time did not exactly match the actual operation time. However, I thought that tourniquet time reflects the actual surgical time because both simultaneously started when I started the procedure and ended before I left the operation room. Sixth, this study is a single-surgeon series; therefore, it is necessary to consider the single-surgeon factor compared with multiple surgeons to show broader validity. However, a single-surgeon study may also have an advantage, given that the surgeon factor could be excluded from the factors that cause glove perforation.

Proportion of Procedures With Glove Perforation

In this study, approximately one in five foot and ankle operation procedures resulted in at least one perforated glove. A previous study revealed that the intraoperative

glove perforation proportion can vary between 12% and 52% [10, 12, 13, 16]. Various factors might affect glove perforation, such as the type of procedure, surgeon factors, and operation time. Therefore, the reported glove perforation proportion could be affected by the study design. The present study focused on adjusting several factors that are potential influencing factors. To the best of my knowledge, this is the first study to investigate the perforation proportion of gloves used by a single surgeon during foot and ankle procedures. The overall glove perforation proportion was 19%. This was similar to the glove perforation proportion in hand surgery and was low compared with the proportions in other orthopaedic operations (18.5% to 48%) [3, 5, 10, 11]. Some factors might affect the relatively low glove perforation proportion in hand and foot and ankle procedures. Hand operations, similar to foot and ankle operations, have a small surgical field compared with those in other orthopaedic operations. Therefore, movement of the hand and fingers intraoperatively is smaller than that in other orthopaedic operations, and I believe this factor could decrease the chance of glove injury intraoperatively.

Factors Associated With Glove Perforation

Longer procedures, not surprisingly, were associated with more damaged gloves; however, procedures performed on bone were not. The latter finding surprised me. I expected that a bone operation, which is likely to expose the gloves to sharp bone fragment and devices, would increase the glove perforation rate. Based on the results of this study, glove perforation owing to sharp instruments (such as Metzenbaum and suture needle), which are used in all operations, seems to occur more frequently than perforation because of sharp bone fragments. To the best of my knowledge, however, there has been no study that compares the glove perforation rate between bone and soft tissue operations. A well-designed study is required to evaluate this issue, and surgeons should pay attention to glove perforation during soft tissue operations as well as bone operations. The present study revealed that 69% of perforated gloves were on the left side. Considering bilateral procedures, the left glove was perforated in 84% of all patients, similar to the result of a previous study [4]. In addition, my data were collected from a single right-handed surgeon; the left hand was my nondominant hand. Therefore, I concluded that gloves on the nondominant hand are a risk factor for glove perforation intraoperatively. Because surgeons generally use surgical devices with the dominant hand, the opposite hand can have a greater chance of glove injury because of the sharp tip of surgical devices.

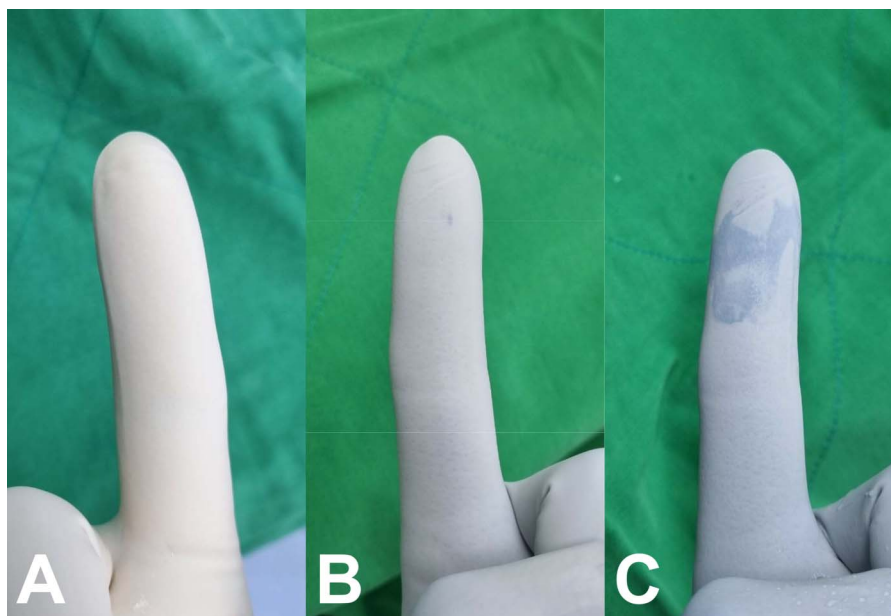


Fig. 3. As shown in these photographs, the outer glove was perforated. (A) In the experimental situation, an outer glove perforation was made using a 26-gauge needle on the index finger. Then, I put my index finger in saline solution and removed it immediately. As shown in the picture, it was difficult to detect glove perforation using the regular double gloving technique. (B) When using colored indicator under gloves, I could visually check damage to the glove. However, if a surgeon were to focus on the procedure, it might be difficult to check glove perforation with this change. (C) When I put my index finger in saline solution for 3 seconds, I could easily detect glove damage. The intraoperative use of a colored indicator under glove in a fluid-rich environment makes it easier to detect glove perforation.

Did Colored Indicator Gloves Increase the Detection of Glove Perforation?

The use of indicator gloves increased the intraoperative detection of glove perforations. In this study, the detection proportion in the indicator under glove group was higher than that in previous work reporting that surgeons were aware of intraoperative perforation in 15% to 50% of procedures [15-17]. Detecting glove perforation intraoperatively could be affected by the user's sensitivity and the type of operation being performed. For example, an operation for open fractures or diabetic foot uses a large amount of fluid irrigation, and the pattern of water permeation through the outer glove can increase the detection rate of glove perforation. In the current study, in the indicator under-glove group, outer glove perforation was found more easily because the glove color at the perforation site changed dramatically in a fluid-rich environment (Fig. 3). However, during arthroscopy, surgeons may pay less attention to their gloves because they look at the monitor rather than at their hands. For this reason, I randomized the types of gloves used in this study. However,

using an indicator under glove did not decrease the under-glove perforation proportion. Because most of the perforations occurred in the outer gloves, I expected that the under-glove perforation rate might be lowered when outer-glove perforation is detected earlier. However, according to the present study results, intraoperative under-glove perforation does not seem to occur sequentially after outer-glove perforation, but it occurs simultaneously. Even if outer-glove perforation was detected, under-glove perforation could not be confirmed during the operation. Thus, I recommend replacing the under glove when damage to the outer glove is found. Although it is difficult to interpret the study results because of the small number of under-glove perforations, the study confirmed that an indicator under glove increases the detection proportion of outer-glove perforation; therefore, the unrecognized under-glove perforation proportion might also be lowered when the outer and under gloves are replaced simultaneously. Glove perforation does not mean contamination [14]. However, I believe the surgical team should consider replacing both gloves simultaneously to reduce the proportion of intraoperative infection.

Conclusion

The present study showed that surgical glove perforation occurred in approximately one of five procedures during foot and ankle procedures. I recommend using colored indicator under gloves and replacing the under glove when replacing the outer glove after perforation to reduce contamination related to glove injury. Future studies are warranted on the effect of glove perforation on clinical infection.

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