DOUBLE GLOVING FROM A TOTAL COST PERSPECTIVE

- *PINHOLES IN GLOVES ARE MORE PREVALENT THAN EXPECTED AND ARE A FACTOR IN THE INCREASED INCIDENCE OF SSI.*
- *DOUBLE GLOVING AS AN SSI COUNTERMEASURE CONTRIBUTES TO A REDUCTION IN MEDICAL COSTS.*

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The Japanese Society of Gastroenterological Surgery:	Specialist, Instructor
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Japanese College of Infection Control Doctors:	Infection Control Doctor

1 Presence of pinholes before and during use

Pinholes are present before use

Tiny holes (pinholes) are sometimes already present in gloves before they are used. In Japan, quality standards are stipulated by the Japanese Industrial Standards (JIS). Acceptable Quality Level (AQL) for pinholes in surgical gloves is 1.5 or less. AQL 1.5 (G1 level) means that, for example, a batch of 10,000 manufactured gloves can be shipped provided that when a sample of 80 gloves is taken from the batch, no more than three gloves are faulty. While 80/10,000 gloves is the representative sample required to meet AQL, it is still possible that pinholes are present in some gloves before use.

Glove perforation occurs in 80% or more of surgical procedures

At the National Defense Medical College Hospital, Dr. Kobayashi, a lecturer in the Department of Medical Safety and Infection Control, led a study in which data from 3,026 gloves used in 162 gastrointestinal procedures (92 laparotomies and 70 laparoscopies) between February 18 and May 15, 2019 was collected and checked for pinholes. In addition to the overall incidence of pinholes, other data such as the relationship between time wearing gloves and perforation was referenced and verified, including the rate of occurrence by surgeon and by case. The results for the rate of perforation per case indicated just how frequently pinholes are formed in gloves when in use. Specifically, *when gloves from 162 surgical procedures were examined, at least one glove was perforated for an indivdual participating in the case 82.1% of the time (133/162).*[1] Due to the risk of pinholes and perforation occurring before and during use, it is important to wear two pairs rather than one pair of surgical gloves, as an infection countermeasure.

2 Meaning of double gloving within the guidelines

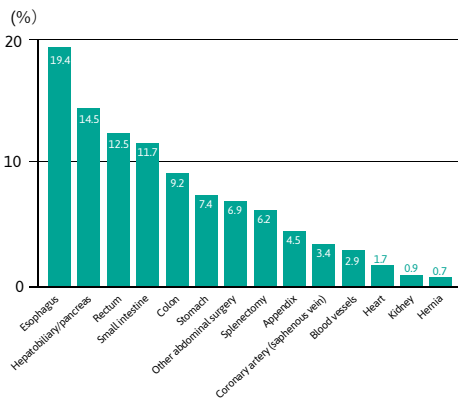
Recommended double gloving in the guidelines

In Japanese guidelines, double gloving is mentioned in (1) ***Guidelines for Infection Control in University Hospitals*** (5th edition) edited by the Japan Infection Prevention and Control Conference for National and Public University Hospitals; (2) ***Guidelines for Implementation of Operative Medicine*** (3rd edition) edited by the Japanese Association of Operative Medicine; and (3) ***Guidelines for Perioperative Management to Prevent SSI in Gastroenterological Surgery 2018*** edited by the Journal of Japan Society for Surgical Infection; all guidelines recommend double gloving for surgery.[2] The ***Guidelines for Perioperative Management to Prevent SSI in Gastroenterological Surgery 2018*** states: *Although there is no clear evidence that double gloving is useful in reducing the occurrence of SSI, it is indicated that double gloving may reduce occupational infection and therefore is recommended from a safety perspective. (A: high-quality evidence, 2b: no scientific evidence but implementation is recommended).*

SSI in Japan

As shown in Figure 1, the SSI incidence for surgical procedures in Japan is high for surgery in the gastrointestinal region.

Figure 1. SSI incidence in Japan



JANIS January 2019 to June 2019, number of medical institutions subject to aggregation: 714 institutions, 138,592 cases

3 Advantages of double gloving from a cost perspective

Correlation between incidence of pinholes and SSI

Studies show there is a correlation between pinholes in gloves and the incidence of SSI. Figure 2 reports data showing the use of gloves with pinholes results in about double the number of SSI incidences.[5]

Bundle of SSI countermeasures for open heart surgical procedures

Verification of SSI preventative effects from the addition of new SSI countermeasures was performed on 179 cases from August 2011 to February 2013 at hospitals with more than 500 regular beds. Countermeasures studied included full-body wiping with chlorhexidine on the day before the procedure; for coronary bypass only, prophylactic administration of vancomycin; disinfection of the surgical area using a chlorhexidine preparation containing alcohol; use of film dressing (without gauze); stopping of wound disinfection from the day after surgery; and double gloving. Through the use of these measures, SSI incidences showed a statistically significant (P = 0.048) reduction from 8.99% (89 cases) before implementation of the new measures (April 2012) to 2.22% (90 cases) after implementation (from May 2012). Similarly, mediastinitis dropped from 4.49% to 0% (P = 0.041).[6] The cost of implementing these measures was 3,300 yen per patient as seen in Table 1.

SSI countermeasures and surgical costs

As mentioned above, the cost of the SSI countermeasures was 3,300 yen per patient; however, given the average cost of an SSI incident was 856,319 yen, the countermeasures are economically effective as explained in Figure 3. When all the countermeasures are introduced for surgery at a cost of 590,700 yen (3,300 yen × 179 cases), the incidence of SSI dropped from eight cases to two cases and the occurrence of mediastinitis from four cases to zero cases. This clearly resulted in lowering medical costs by at least 4.5 million yen (856,319 yen × 6 cases - 590,700 yen).

Increase of post-operative medical costs due to SSI.

When an SSI occurs, the number of hospitalization days increases generating additional costs. Figure 3 shows results of a matched case control study using the same conditions by a number of hospitals. According to the results of the study, it is clear that the occurrence of a SSI results in additional costs of 856,319 yen.[7]

Summary of double gloving and SSI countermeasures:

1. Pinholes are more prevalent in surgical gloves than expected.
2. Double gloving is recommended in the majority of guidelines.
3. Increased medical costs associated with double gloving may be a concern, however total savings are achieved due to lower incidence and costs related to SSI.

Figure 2. Total of 4,147 surgical procedures: Includes various types of regular surgery and vascular surgery

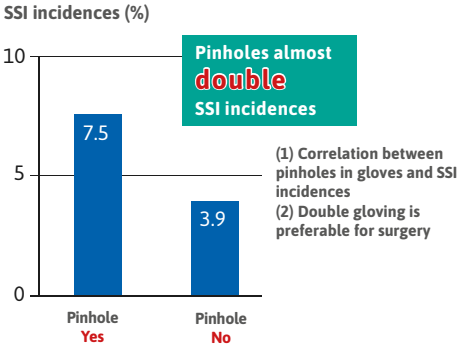
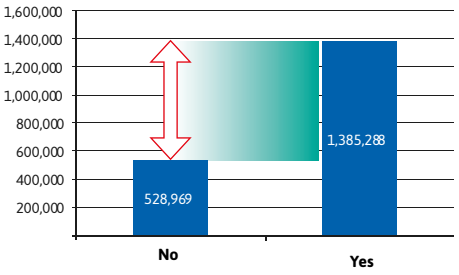


Table 1

SSI countermeasures	Costs
Chlorhexidine	10 ml = 40 yen
Vancomycin	1 g = 1,400 yen
Hexizac alcohol	100 ml = 460 yen
Three surgeons Conditions: Double gloving at 100 yen per pair, outer gloves changed once during surgery (two pairs/person), inner gloves not changed (one pair/person)	100 yen × twice + under glove (100 yen) × 3 surgeons = 900 yen (double gloving)
Film dressing	500 yen
Total	**3,300 yen**

Figure 3. Comparison of medical cost per patient with and without SSI for various procedures, including surgery



Study by the Japan Society for Surgical Infection,
"SSI and medical cost research group"
Conditions: Multicenter, collaborative, matched case control study, from April 2006 to March 2008, 10 centers, 300 matches (600 cases)
CABG (38), valve replacement (16), total gastrectomy (56), appendectomy (62), hepatectomy (44), pancreato-duodenectomy (46), colectomy (204), proctectomy (130), hysterectomy (4)
Each case was matched with an SSI case at same facility, for same surgery, same sex of patient, age ± 5 years, and closest in date

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