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# GLOVE FAILURE IN ELECTIVE THYROID SURGERY: A PROSPECTIVE RANDOMIZED STUDY

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**Abstract**
**Objectives:** To analyze perforation rate in sterile gloves used by surgeons in the operating theatre of the Department of Endocrinological and General Surgery of Medical University of Lodz. **Material and Methods:** Randomized and controlled trial. This study analyses the incidents of tears in sterile surgical gloves used by surgeons during operations on 3 types of thyroid diseases according to the 10th revision of International Statistical Classification of Diseases and Related Health Problems (ICD-10) codes. Nine hundred seventy-two pairs (sets) of gloves were collected from 321 surgical procedures. All gloves were tested immediately following surgery using the water leak test (EN455-1) to detect leakage. **Results:** Glove perforation was detected in 89 of 972 glove sets (9.2%). Statistically relevant more often glove tears occurred in operator than the 1st assistant ($p < 0.001$). The sites of perforation were localized mostly on the middle finger of the non-dominant hand (22.5%), and the non-dominant ring finger (17.9%). **Conclusions:** This study has proved that the role performed by the surgeon during the procedure (operator, 1st assistant) has significant influence on the risk of glove perforations. Nearly 90% of glove perforations are unnoticed during surgery.

**Key words:**
**Thyroidectomy, Surgical gloves, Surgeon, Glove failure, Elective surgery, Thyroid surgery**

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## INTRODUCTION

Exposure to blood pathogens among medical personnel is a serious hazard, which should be 1st and foremost to prevent [1,2]. Personal protective equipments, including gloves, are the main barriers against bloodborne infections among medical personnel. Medical gloves act as a protective barrier to protect medical personnel and their patients from infections during emergency procedures. They protect against bloodborne pathogens, such as human immunodeficiency virus (HIV), hepatitis B virus (HBV) or hepatitis C virus (HCV). The risk of acquiring a virus from 1 percutaneous needle stick is 0.3–0.4% for HIV, 6–30% for HBV, and 2.7–10% for HCV [2–5].

Compared to other clinical fields, surgeons are at a higher risk of glove perforation due to the frequent manipulation of surgical instruments and the use of sharp tools during operative treatment. Therefore, there is a need for highly durable and perforation-resistant gloves.

Several studies have reported the incidence of glove perforation during surgery procedures to be between 3% and 60% [6–9]. The use of medical gloves is also the subject of research of many organizations dealing with the safety of medical personnel, including the Centers for Disease Control and Prevention (CDC). Prior studies have demonstrated an association between glove perforation and duration of the procedure, specific portions of the procedure and hand dominance [5,10,11]. However, the incidence of glove perforations in elective thyroid surgery has not been previously reported. The purpose of our study was to analyze tears in sterile surgical gloves used by surgeons in theatre of the Department of Endocrinological and General Surgery of Medical University of Lodz.

## MATERIAL AND METHODS

An observational cohort study was performed. The study material comprised gloves used by the surgeons in elective thyroid surgery operations at operation theatre of Department of Endocrinological and General Surgery of Medical University of Lodz. The study was conducted from October 2012 to January 2014. The participants of the study included 15 surgeons (operators and assistants). All of the surgeons and surgical assistants participating in this study were right-handed.

### Gloves used in the study

Gloves included in the study were Conformité Européene (CE)-certified and complied with EN 455, 1-3 [12]. The study used 2 types of gloves:

– sterile latex gloves “Sampermed Classic” (prod. Semperit Technische Produkte Gesellschaft mbH, Germany);
– gloves “DermaGel” (prod. Mercator Medical SA, Poland).

Glove size was chosen according to personal preferences of the members of the surgical team. Type of gloves used during surgery were selected at random.

### Study design

In the analysis, the procedures were classified into 3 groups, depending on the diagnosis made using the International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) [13]. Total thyroidectomy with lymph node dissection was performed in case of C73 diagnosis (malignant neoplasm of thyroid gland), while partial thyroidectomy was done in the case of E04.2 (nontoxic multinodular goiter) and E05.2 (thyrotoxicosis with toxic multinodular goiter) diagnosis. During the surgery 3 factors were analysed: the localization of the glove tear, the fact whether the glove tear was noticed by the surgeon during an operation and in whose glove the tears occurred: operator’s or first assist’s. In addition, the collected research material includes variables such as surgeon work experience (in years) and the number of surgeries performed by the same operator on a given day.

A water leak test (WLT) was performed immediately after surgical procedures by doctors who were directly involved in them. During the study it was documented that the gloves were exchanged as a result of damage. If the gloves were visibly perforated during the procedure, regardless of the fact that they were exchanged for the same type and size, the original gloves were also used for the study.

Gloves were tested using the approved standardized water-leak test method EN455-1 [12]. This method involves filling of 1000±50 ml of water at a temperature of 15–35°C to the glove (allowing the water to pass freely into the glove) and then observing it for 2 min in order to detect possible leaks. The location and number of perforations were recorded.

In order to confirm the good quality of the gloves, the authors tested a random sample as the control. They performed the WLT for 50 sets of Sampermed gloves and 50 sets of DermaGel gloves. The prevalence of glove perforation before use was 0%.

### Statistical methods

All data collected were analyzed using Statistical Package R for Windows (version 3.0.0). Data was analyzed using $Chi^2$ test and Fisher's exact test. P values of 0.05 or less were considered significant.

## ETHICS

The study was approved by the Ethics Committee of Medical University in Łódź, Poland (dec. No. RNN/549/13/KB). Participation in the study was voluntary. All the surgeons and surgical assistants expressed their consent to take part in this study.

## RESULTS

Altogether, 321 surgical operations (endoscopic thoracic sympathectomy – ETS) were included in this study (Table 1).

During 321 ETS, we examined 972 pairs of gloves from surgeons. Gloves were changed when any damage had been noticed. The only damages noted by surgeons were perforations and rips. Total number of damaged pairs of gloves during 321 surgical operations was 89, including 9 pairs (perforations noted during operations) with obvious tears, and 80 pairs (unrecognized perforations during operations) which failed the water test.

Glove perforation was discovered during ETS only in 9 of 89 perforated glove sets (10.1%). The 34 (38.2%) of glove set perforations were detected after surgery during visual inspection prior to the water leak test. During WLT were found 46 previously unrecognized glove perforations (51.7%). The overall perforation rate was 9.2% (89 perforations in 972 glove sets).

The highest tear rate, irrespective of the role performed by the doctor in the surgical team, was observed for the following procedures by ICD-10 code: E04.2 – 5.55%, E05.2 – 4.45% and C73 – 4.32% (Table 2). In ETS for non-toxic multinodular goiter (E04.2), thyrotoxicosis with toxic

**Table 1.** Surgical procedures in accordance with ICD-10

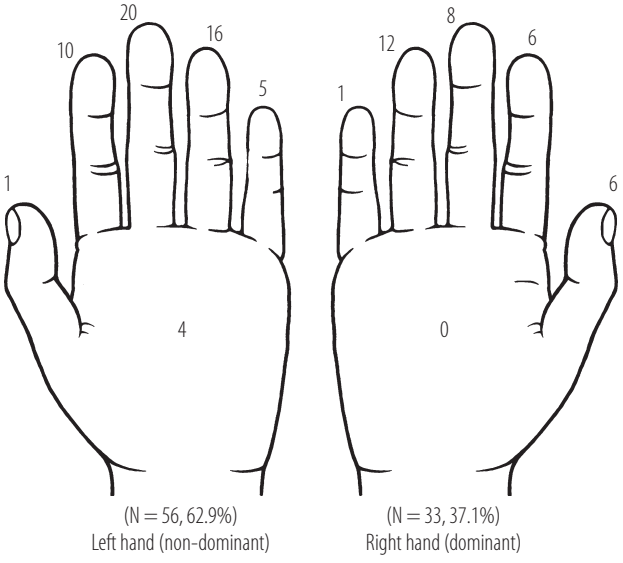
| ICD-10 | | Procedures (total) (N = 321) | | First 10 procedures [%] |
|---|---|---|---|---|
| code | description | n | % | |
| E04.2 | nontoxic multinodular goiter | 192 | 59.8 | 60.6 |
| E05.2 | thyrotoxicosis with toxic multinodular goiter | 83 | 25.7 | 30.8 |
| C73 | malignant neoplasm of thyroid gland | 46 | 14.5 | 8.6 |

ICD-10 – The 10th revision of International Statistical Classification of Diseases and Related Health Problems.

**Table 2.** Glove tears by ICD-10 code and role of medical personnel during the procedure

| ICD-10 | | Glove tear rate [%] | | | | Procedures [n] |
|---|---|---|---|---|---|---|
| code | description | irrespective of the role of medical personnel | operator | 1st assistant | 2nd assistant* | |
| E04.2 | thyroidectomy | 5.6 | 16.7 | 0.0 | 0.00 | 15 |
| E05.2 | thyroidectomy | 4.5 | 8.9 | 4.7 | 0.00 | 118 |
| C73 | thyroidectomy | 4.3 | 9.7 | 3.5 | 0.00 | 72 |

* Second assistant did not participate in the performance of this type of procedures.
Abbreviations as in Table 1.




Numbers – number of glove damages and their locations.

**Fig. 1.** The most frequent localization of glove perforation

multinodular goiter (E05.2) and malignant neoplasm of thyroid gland (C73), operator had the highest perforation rate, 16.7% vs. 8.9% vs. 9.7%, respectively. Percentages of glove perforations of 1st assistant were 0% vs. 4.7% vs. 3.5%, respectively. The differences between the frequency of glove perforations of operator and 1st assistant were statistically significant in the case of ETS for E04.2 ($p < 0.001$), E05.2 ($p < 0.001$) and C73 ($p < 0.001$).

The quantities of the gloves used were as follows: 1214 pcs. (607 sets) Sempered gloves and 730 pcs. (365 sets) Dermagel gloves. The overall tear rates for Sempered and Dermagel gloves were 3.8% and 5.5%, respectively. This difference was not statistically significant ($p = 0.17$).

The location of the holes in perforated gloves are shown in Figure 1. The most common site of perforation was the middle finger of the left hand (22.5%), the 2nd most common was the left and right ring finger with 16 (17.9%) and 12 (13.5%) perforations, respectively. Perforations were more common on the nondominant than the dominant hand (56 vs. 33, $p < 0.001$).

Additional analysis of the research material did not show statistically significant correlation between the frequency of glove perforations and work experience ($p > 0.05$).

## DISCUSSION

The prevalence of blood-borne diseases, such as HIV, HBV or HCV is increasing worldwide. Surgeons are at risk of contracting infectious diseases from their patients if the integrity of surgical gloves is compromised [14]. The study presented here showed the high glove perforation rate (9.2%). This may increase the risk of exposure to infectious diseases. The perforation rate of surgical gloves is reported to range from approximately 3% to over 60% depending on the type of surgery [6–9].

During thyroidectomy for nontoxic multinodular goiter (E04.2) percent damage to the operator gloves (16.7%) is lower than that reported by Driever et al. amongst

cardiac surgeons [15]. Our results confirmed that the frequency of glove perforations was significantly higher in operator than 1st assistant; this difference is confirmed by other studies [9,15,16].

The site of perforation seems to related to the role of task in surgical team both according to our own and the literature data [9]. In this study the middle finger an ring finger on the left hand of the surgeon were most likely part of glove to be punctured or torn. Other studies have shown similar results [4,9,17]. That is because surgeons usually hold sharp tools in the right hand, and it can lead to accidental damage to the left glove. In our study, the middle finger of the left (non-dominant) hand was also the most common site of the damage, with 16 of 89 perforations (17.9%).

Damage to the glove was visible in 43 of the 89 perforations, but the surgeon noticed glove perforation during operations only in 9 cases. Forty-six of 89 perforations were identified solely by water leak test. This means that more than 1/2 of glove perforations are invisible to the eye. The large number of unnoticed glove perforations (UGP) confirmed the findings of other authors, among whom UGP reaches up to 100% [4,17,18]. Naver and Gottup [19] indicates glove perforation detection during surgery at 50%, whereas the corresponding value reported by Laine and Aarnio is 37% [20]. These results indicate the need for the use of more resistant or double gloves. The protection rate offered by double gloving was reported in various studies [4,21,22].

This study has several limitations. First, we only focused on thyroid operations, so future studies will be needed to investigate other types of surgeries. Second, we did not check the time of perforation during the operation. However, Demircay et al. [23] reported that operation time was not clearly related to the perforation rate, notwithstanding the perforation rate was higher in the 1st half of the operation. In turn, other researchers indicate that the perforation rates increase over time [20,24]. Guo et al. [19] in their studies showed that the mean perforation time was about 70 min after startup of the operation. Other researchers also showed that the rate of perforation increased when gloves were worn longer than 60 min [17,25]. This time may depend on the type of surgery and requires further study.

Without a doubt, research results quoted in this publication, both our own and of other authors suggest that the risk of blood-borne infections in the surgeon's work is the current problem. It is, therefore, worth considering the introduction of widespread use of double gloves (with puncture signaling system) for surgeons.

Parkinson and Tanner recommend double gloving to minimize the risk of perforation and possible cross infection [26]. They analyzed 10 papers devoted to this problem and concluded that there was an 11% probability of perforating a 1-layered glove during low-risk surgical procedures [26]. In the study by Laine et al. surgical gloves were perforated in 8% of the cases [27].

In turn, Caillot et al. pointed out that a high percentage of surgical glove failures (96%) remained undetected [28]. Florman et al. [29] conducted a double-blind randomized study using simulated surgical procedures in order to assess the average time after which the medical personnel detected glove punctures. Perforations were detected after 42 s in 56% of the cases and after 67 s in 12% of the "procedures" [29].

The Copernicus Memorial Hospital in Łódź does not have a glove failure risk classification or double gloving regulations (procedures) for high-risk surgery. The decision to wear double gloves is made by operators and assistants individually.

The data reported by Tanner suggest that double gloving minimizes the number of inner glove perforations to 3% [26]. Laine et al. claim that in the double glove system the inner gloves were punctured in 6 out of 88 outer glove perforations (6.82%) [27]. These facts mean that the use of double gloves by operators can decrease the percentage of inner glove punctures 3- to 6-fold, thus minimizing the risk of medical personnel becoming infected

by contagious diseases transmitted through the patients' blood, as well as the risk of infecting the patients' with the pathogens present on the hands of the medical personnel.

## CONCLUSIONS

These results suggest that total thyroidectomy surgery is a procedure with a high risk of damage to the glove, and the surgeon performing the operator role is the most exposed member of the surgical team. Every 10th glove perforation is detected during the operation, and every 2nd glove perforation is invisible to the eye and recognizable only during the water leak test.

Further studies that examine the perforation rate in relation to surgical treatments are required to help prevent infection and disease transmission among surgeons.

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