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Surgical glove perforation during intramedullary nailing of intertrochanteric fractures

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Intramedullary nail fixation is a routine procedure for treatment of intertrochanteric fractures. Aseptic technique is vital for reducing postoperative complications, as intraoperative glove perforations increase the risk of surgical site infections. The aim of this study was to determine the incidence of surgical glove perforation during intramedullary nailing of intertrochanteric fractures and to identify surgery-specific steps at risk. A prospective series of 148 short intramedullary nail implantations was analysed. Intraoperative glove perforations and causative events were recorded. All gloves from the scrubbed surgical team were collected and examined for micro- and macroperforations. 1771 gloves were tested. A total of 341 perforations in 309 gloves were detected, resulting in an overall glove perforation rate of 17%. Surgeon experience had no influence on the overall incidence of glove perforations. Usage of the awl and insertion of the proximal locking screw resulted in 33.9% of all detected glove perforations. Perforation rate significantly increased with operative time ($p = 0.003$). Regular glove changing after surgery-specific risk-steps and during longer surgeries could decrease the rate of glove perforations during intramedullary nailing of intertrochanteric fractures and reduce the risk of potential septic contamination or even disease transmission for both, the surgeon, and the patient.

Trauma surgery has to face a tremendous increase in hip fractures during the next decades[1,2]. Intertrochanteric fractures represent the majority of hip fractures and occur with similar frequency as fractures of the femoral neck[3]. Especially due to its minimally invasive nature and short operative times, Intramedullary nail fixation emerged as one of the most common methods of internal fixation for intertrochanteric fractures[4,5]. While some studies suggest superior Harris Hip Score 6 months after hip arthroplasty, patients treated with intramedullary nailing show higher Harris Hip Score results one year after surgery. Additionally, nailing of intertrochanteric fractures is associated with shorter operative time and less blood loss[6]. Early surgical treatment within 24 h is the mainstay of treatment in order to reduce mortality and complication rates[7–10]. Nevertheless, hip fracture patients are susceptible to developing a variety of post-operative complications including surgical site infection (SSI)[11]. A strict aseptic technique is essential to reduce the risk of surgical field contamination. Hand hygiene and the use of sterile surgical gloves and gowns are standard care in any surgical procedure. Nevertheless, surgical glove perforation may pose a potential risk for strike-through contamination[12]. The use of high-quality sterile gloves provides protection for both the patient and the surgical team. The transmission of bloodborne pathogens like HIV, Hepatitis B and C, or new and unknown pathogens is especially a matter of concern in the acute surgery setting[13–15]. HIV is estimated to have a global prevalence of 0.85% and Hepatitis C virus affects 1–2% of the population worldwide, both conditions have higher prevalence in specific regions, such as sub-Saharan Africa[16,17]. These infectious diseases pose a significant risk, especially given the frequency of hip fracture surgeries, which are often performed urgently in an acute care setting, making pre-surgical virologic testing not routinely available. However, pre-operative testing does not reduce the potential exposure to the surgical team. Most surgeons underestimate the risk of disease transmission from bloodborne pathogens and rarely report needlestick injuries[18]. Glove perforation rates are reported to be especially high in orthopedic surgery involving total joint replacement, fracture reduction, and the use of rotatory instruments[19–22]. Double-gloving has therefore been advocated and recommended for orthopedic surgery[23]. Several studies examined the influence of operative time, hand dominance, and high-risk events on glove perforation[19,22,24–27]. However, to date, no study has specifically examined the incidence of glove perforation during nailing of intertrochanteric fractures. Since this surgery is usually a fast and fluoroscopy guided procedure, not involving open fracture

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reduction, other potential risk factors for glove injury may play a significant role. This prospective study aimed to determine the incidence of surgical glove perforations in the scrubbed surgical team (surgeon, assistant, scrub nurse) and to further analyse surgical steps at risk to injure the gloves.

Materials and methods

Study design

Surgical gloves from implantation of intramedullary nails for intertrochanteric femoral fracture treatment between December 2018 and January 2020 in a Level-I-trauma centre were collected prospectively. Our routine departmental practice comprises double gloving for all orthopedic trauma procedures. The selection of glove pairing, such as the use of inner layer indicator gloves, depends on the preferences of surgeons or scrub nurses. For the outer layer or both layers white latex gloves (Sempermed® Supreme) and for the inner layer green indicator gloves (Sempermed® Supreme Green) were used. In case of a known latex allergy of the patient, latex free gloves were used. The glove manufacturer´s instructions state that surgical gloves were tested to potential pinholes during the quality process. The Sempermed® surgical gloves show a 0.65 AQL (Acceptable Quality Level) for freedom from pinholes, examined during water leak test[28]. An AQL of 0.65 means a high standard of quality with a limit of no more than 0.65% defective gloves in the whole order quantity on average.

Given our inclusion criteria we enrolled patients who were treated for a primary intertrochanteric fracture treatment using an intramedullary short nail. Revision surgeries were excluded. All patients gave informed consent to be enrolled in this project and were 18–90 years old. The study was approved by the institutional ethics committee and was performed in accordance with the declaration of Helsinki. In our department two cephalomedullary nails are routinely used, the proximal femoral nail antirotation (PFNA® 200 × 11 mm, DePuy Synthes, Umkirch, Germany) and the gamma nail (Gamma3® 200 × 11 mm, Stryker Trauma, Murnau, Germany). Implantation of a cephalomedullary nail was performed under dual-plane fluoroscopy using two C-arms (one for the anterior–posterior view, and one for the axial/lateral view), on a fracture table. Exclusion criteria comprised operations of patients with known transmittable infectious diseases (i.e.,HIV or hepatitis B or C) and revision surgery (i.e. exchange of implant or implant removal). Hand dominance, glove sizes, and pairing (i.e., use of indicator gloves) was evaluated for each team member of the operation. The surgical teams consisted of a surgeon, an assistant and a scrub nurse. The surgeons and assistants experience in intertrochanteric fracture treatment as determined by staff position (senior, consultant, resident, student), the operative time, the used implant, the side of the operation, and intraoperatively detected glove perforations were recorded. Also, the intraoperative procedure/step which led to glove puncture or perforation was analysed.

Glove collection

Operation room personnel and orthopedic trauma surgeons were informed and educated regarding study design and collection procedures. Study protocol and dedicated labelled plastic bags for glove collection were placed in each operating room. Each team member placed the used gloves after the operation in a separate plastic bag. Additional plastic bags for noticed intraoperative glove perforations were also available. In case of a noticed glove injury with following glove exchange, the injured glove was placed in a "glove injury bag" indicating the injured region, and if known, the mechanism of injury (i.e., cannulated placement of the femoral head guide wire; insertion of the proximal locking screw; etc.). An accompanying study protocol with a schematic drawing of a hand was used to document glove injuries and basic data of the surgery (i.e., side of operation). Gloves that were discarded and exchanged due to reasons of sterility, were also collected. The surgical gloves were stored in separate clean plastic bags and tested within 1 week of collection[29]. Outer and inner layer gloves could be easily differentiated by the degree of soilage, or the use of indicator gloves. All gloves were counted individually and not as a pair for further analyses.

Water fill test

All gloves were tested for detection of holes in surgical gloves using a water fill test according to the gold standard approved by the FDA (Food and Drug Administration) and European standards, described by the American Society for Testing and Materials (ASTM International)[30]. This test method is limited to the detection of holes that allow water leakage under the conditions of the test. Two holes were drilled in the proximal end of a 5 cm inner diameter and 38 cm long plastic tube (polyvinyl chloride (PVC) pipe) to allow suspension of the tube with rope or wire. At the distal end of the tube, a thick rubber ring and a reusable cable tie secured the glove during testing. The tube was mounted in a vertical hanging position and each tested glove was fixed to the testing tube by stretching the cuff around the distal end. Care was taken that the outer surface of the glove was completely dry. Afterwards, 1 L (1000 ml) of room tempered tap water (15 to 30 °C) was poured into the top of the testing tube and caught by the glove. Blue ink was added to the water to theoretically increase the sensitivity of glove perforation detection[31]. The setup of the water fill test is visualized in supplemental figure 1. The glove distended due to the water fill and perforations could be recognized easily as water leakage seen as droplets forming at the tip of a digit, or a thin stream of water at the site of glove injury. A representative image of a glove positive for perforation is given in supplemental figure 2. This test method is limited to the detection of holes that allow water leakage under the conditions of the test. Holes that were already detected by visual inspection of the glove (> 5 mm) were classified as macroperforations. All other revealed perforations during the water fill test were classified as microperforations. A stopwatch with a timer was used to stop 2 min of observation time of the water fill test. Every detected hole was documented accordingly. The region of the glove perforation was classified into finger 1 to 5 (F1-5), and the palm of the hand (H) as separate region.

Glove perforation rate

In this study, glove perforation rate was assessed using three metrics: overall glove perforation rate, surgical perforation rate, and mean perforation rate. The overall glove perforation rate represents the percentage of gloves with at least one perforation out of all gloves used in all surgeries. Surgical perforation rate indicates the proportion of surgeries in which at least one team member experienced a glove perforation. Mean perforation rate represents the average number of glove perforations observed across all gloves used by team members during each surgery.

Statistical analysis

All statistical analyses were performed in R (version 3.6.1). We analysed the influence of hand dominance, type of implant, operation side, surgical time, glove layer, the surgeon´s experience level, and surgical team member position on perforation rate and site. Normal distribution was assessed by Shapiro–Wilk test. Kruskal–Wallis and Mann–Whitney-U test were used for data analysis. Post-hoc testing was conducted by use of Dunn Test. Fisher's test and Chi-Square-Test were implemented for categorical variables. Total count (n) of perforations and perforation rates were reported by percentage (%). 95% confidence intervals for the mean perforation rate per surgery were calculated using a Bootstrap resampling method with 1000 simulations in XLSTAT. For all tests, a p value of <0.05 was considered statistically significant.

Results

The study enrolled 148 consecutive implantations of intramedullary femoral nails (106 PFNA, 42 gamma nails). A total of 1771 used surgical gloves (864 pairs, 31 single left, and 12 single right) including 651 from surgeons, 502 from assistants, and 618 from scrub nurses were collected and screened for glove perforations. 919 were outer gloves (including 8 latex-free gloves) and 844 inner gloves (including 216 indicator gloves and 8 latex-free gloves). The remaining used gloves were white latex gloves.

Perforation rates

A total of 341 perforations in 309 gloves were detected in 126 surgeries, resulting in an overall glove perforation rate of 17.4% (309/1771 gloves). In 107 of all included fracture fixations at least one team member sustained a glove perforation leading to a surgical perforation rate of 85.1% (107/126). The mean perforation rate per surgery was 2.13 (95% CI 2.0–2.6) (Table 1). Out of all perforations detected by the water fill test 19.1% (65/341) were macroperforations, and 80.9% (276/341) were microperforations (Table 2).

Surgical team

In comparison with the assistants and nurses, surgeons showed the highest rate of glove perforations (Table 1). In 66.9% of all surgeries (99/148), the surgeon had at least one glove perforation. Overall perforation rate for surgeons was 25.8% (168/651 gloves), as well as 12.6% (78/618 gloves) for nurses and 12.5% (63/502 gloves) for assistants (Table 1). The incidence of micro- ($p=0.007$) and macroperforations ($p=0.002$) between surgical team members was also different. Surgeons' gloves were more prone to experience micro- and macroperforations than assistants' ($p=0.003$, $p=0.006$) and nurses' ($p=0.003$, $p=0.004$) (Table 1).

Level of experience

A total of 119 (80.4%) nail implantations were performed by residents, followed by 15 (10.1%) performed by senior consultants, and 14 (9.5%) by consultants. The level of experience ("resident" vs. "consultant" vs. "senior") did not affect the incidence of glove perforation, neither within surgeons ($p=0.938$) nor within assistants ($p=0.534$) (Supp. Table 1).

Perforation pattern

The pattern of the perforation sites differed between the surgical team members. 41.7% (48 micro- and 30 macroperforations) of all surgeons' perforations occurred on the left index finger and 16% (24 micro- and

Surgical team members	Number of surgical team members	Number of gloves used	Number of perforated gloves	Overall perforation rate[a]	Surgical perforation rate[b]	Mean perforation rate (mean, 95% CI)
All	417	1771	309	17.4%	85.1%	2.13 (2.0–2.6)
Surgeons	148	651	168	25.8%	66.9% $p=0.002$* $p=0.001$**	
Assistants	123	502	63	12.5%	32.5%	
Scrub Nurses	146	618	78	12.6%	39.7%	

Table 1. Glove perforation rates. Detailed information on the participating surgical team members, as well as number of gloves, perforated gloves and different perforation rates. [a]Overall perforation rate = percentage of used gloves that had at least one perforation. [b]Surgical perforation rate = proportion of surgeries in which at least one team member experienced a glove perforation. *Significant compared to nurses. **Significant compared to assistants.

	Number of perforations	%	p value
Surgeons total	187	100%	
Macroperforation	46	24.6%	$p=0.006$*, $p=0.004$**
Microperforation	141	75.4%	$p=0.003$*, $p=0.003$**
Assistants total	71	100%	
Macroperforation	10	14.1%	
Microperforation	61	85.9%	
Nurses total	83	100%	
Macroperforation	9	10.8%	
Microperforation	74	89.2%	
Gloves Total	341	100%	
Macroperforation	65	19.1%	
Microperforation	276	80.9%	

Table 2. Macro- and Microperforations. Number and frequency (%) of micro- and macroperforations depending on the role in the surgical team (surgeon, assistant, nurse). Occurrences of micro- and macroperforations are compared between the team members. *Significant compared to nurses. **Significant compared to assistants.

6 macroperforations) on the right index finger. Likewise, 38% (22 micro- and 5 macroperforations) of all assistants' perforations affected the left index finger followed by the right index finger with 21.2% (14 micro- and 1 macroperforations). On the contrary, within nurses 25.3% (20 micro- and 1 macroperforation) of all perforations were located on the right thumb and 19.3% of all perforations were found on the right index finger (13 micro- and 3 macroperforation). In addition, within nurses 7.2% of all perforations occurred palmar on the right hand while in surgeon's this area was affected in only 3.7% (Fig. 1).

Hand dominance and sides

58.1% of perforations (198/341 perforations) occurred on the left hand and 41.9% (143/341 perforations) on the right hand, respectively. 57.2% (195/341 perforations) were located on the non-dominant, and 42.9% (146/341 perforations) on the dominant hand. The non-dominant hand was involved in 65.2% (121/187 perforations) of surgeons' perforations and 56.33% (40/71 perforations) in assistants. Within scrub nurses 60.24% of perforations occurred on the dominant hand (50/83 perforations) (Supp. Table 2).

Inner versus outer layers

In 24.2% (222/919) of all outer gloves the water fill test revealed at least one glove perforation and respectively in 10.3% (87/844) of all inner gloves. Comparing outer and inner gloves, perforation patterns showed a similar distribution for both. In 40 (46.0%) cases the location of the outer glove perforation matched with the corresponding inner gloves. In 27 cases the corresponding perforations were microperforations, and in 13 cases the corresponding perforations were macroperforations. In general, perforations occurred more frequently on the outer glove ($p=0.01$) (Table 3).

Type of implant

Surgical glove perforation rate was similar when comparing implantation of PFNA 86.8% (92/106 surgeries) versus gamma nail 81% (34/42 surgeries), $p=0.2817$. When examining the occurrence of glove perforations based on the side of the operation (right hip vs. left hip) and the surgeon's hand (right vs. left), we observed a greater frequency of injuries to the left-hand during procedures on the left side. However, this variance did not reach statistical significance ($p=0.630$ for right-sided and $p=0.523$ for left-sided nails) (Fig. 2).

Causes for perforation

Of all glove perforations, 16.4% (59/341) were detected during surgery by a member of the surgical team. The primary surgery-specific mechanism leading to visible glove injuries during femoral nail implantation was the utilization of the awl for entry point determination (19.6%), followed by the insertion of the proximal locking screw (14.3%). Approximately 30.4% of all perforations occurred during tissue preparation or wound closure. Other noteworthy surgical procedures associated with perforations included the use of the drill or the guide sleeve (7.1% each). Moreover, 10.7% of all macroperforations were either identified post-surgery or remained undetected. (Refer to Fig. 3).

Operative time

Surgical procedures with extended operative durations showed a notable increase in the frequency of glove perforations ($p=0.002$). Specifically, a greater number of perforations were observed in surgeries lasting over 60 min in comparison to those lasting 30 min or less ($p=0.008$) and between 31 and 60 min ($p<0.001$) respectively (Fig. 4).

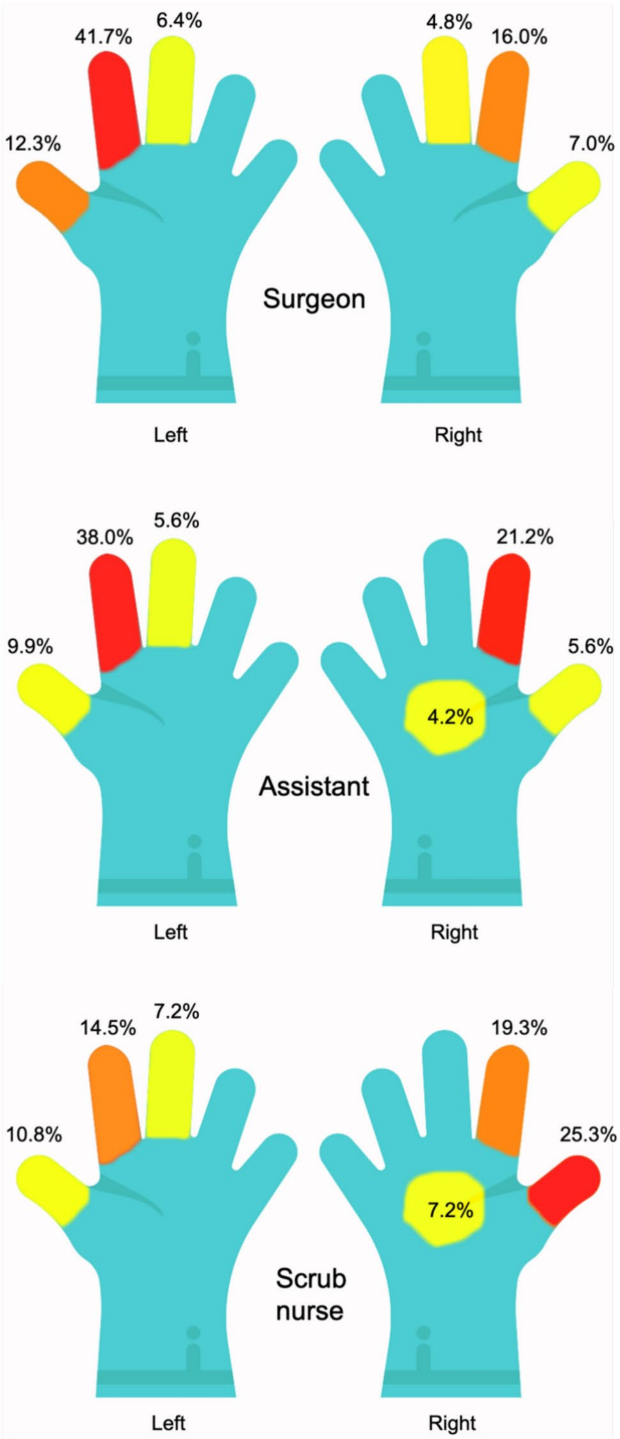

Fig. 1. Perforation pattern for the surgical team members. Glove perforation patterns for each surgical team member. Percentages are given in relation to each operation team member's number of perforations.

	Total perforation (n)	Detected (n)	Detected (%)
Outer gloves	250	35	14%
Inner gloves	91	14	15.4%

Table 3. Detected perforations. Detailed information on detected perforations of the outer and inner gloves.

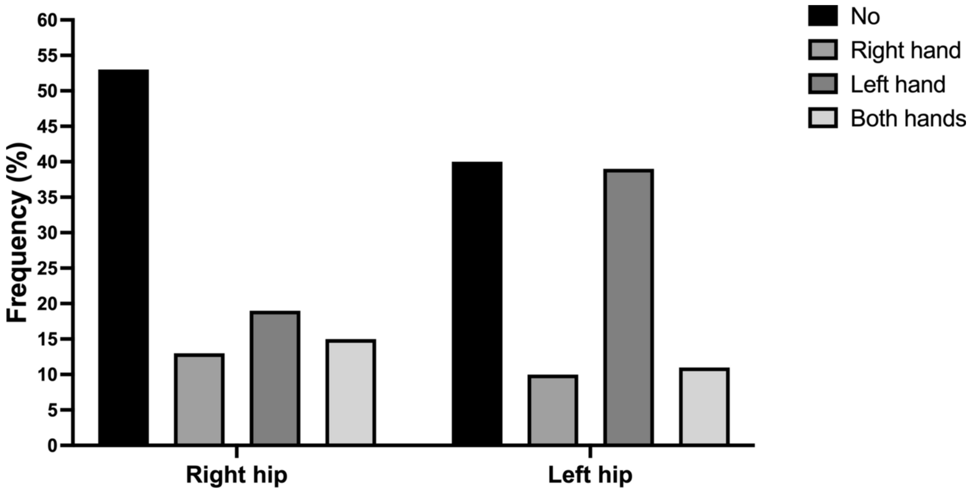

Fig. 2. Influence of operation side and hand dominance on localization of perforation. Frequency (%) of glove perforations depending of the hand used and in relation to the side of the operated hip.

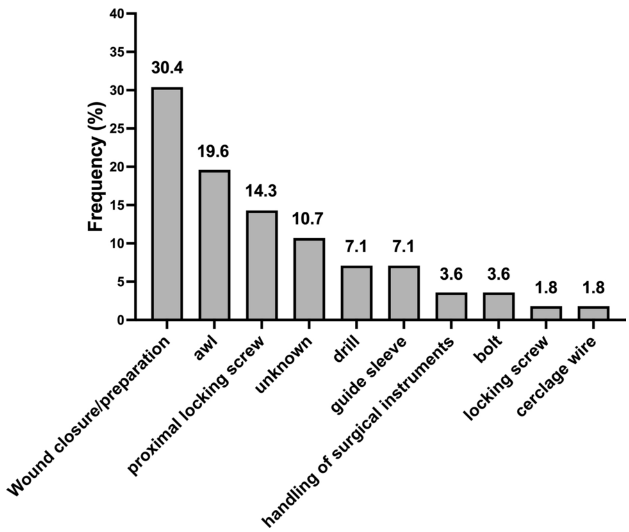

Fig. 3. Surgical steps leading to glove perforation. Frequency (%) of glove perforations during at-risk steps in surgery.

Discussion

The prevalence of hip fractures is anticipated to rise in the coming years, primarily attributed to the growing elderly demographic and a heightened prevalence of osteoporosis[32]. Even though intramedullary nailing of intertrochanteric femoral fractures is a routine procedure, postoperative complications are common and often associated with SSI[33,34]. As intraoperative glove perforation is a likely cause for SSI and especially prevalent during orthopedic surgery, we aimed to better understand the incidence of glove perforation during intramedullary nail fixation[35,36]. In this prospective study, we identified several key aspects of glove perforation during intramedullary nailing of intertrochanteric fractures. The Surgical glove perforation rate was high, which was especially true for surgeons. Surgeons experienced glove perforations more frequently than other surgical team members. Also, specific perforation patterns could be identified for each team member. Surgical steps that were especially prone to cause glove perforation were usage of the awl or the proximal locking screw, as well as wound closure and preparation. Notably, while the surgeon's experience had no impact on the occurrence of surgical glove perforation, longer operations ultimately resulted in an increased glove perforation rate.

Surgical procedures involving significant instrumentation and bone involvement have historically been associated with higher perforation rates[26]. In addition, the incidence of glove perforations during emergency surgery is twice as high compared to elective interventions[19]. Compared to a previously reported incidence of 60% for glove perforations during lower extremity fracture surgery, intramedullary nailing of intertrochanteric fractures can be classified as a procedure with a high risk of glove perforation[37]. In this study focusing only on intertrochanteric fractures in 85.1% of all surgeries at least one glove perforation occurred. While there are

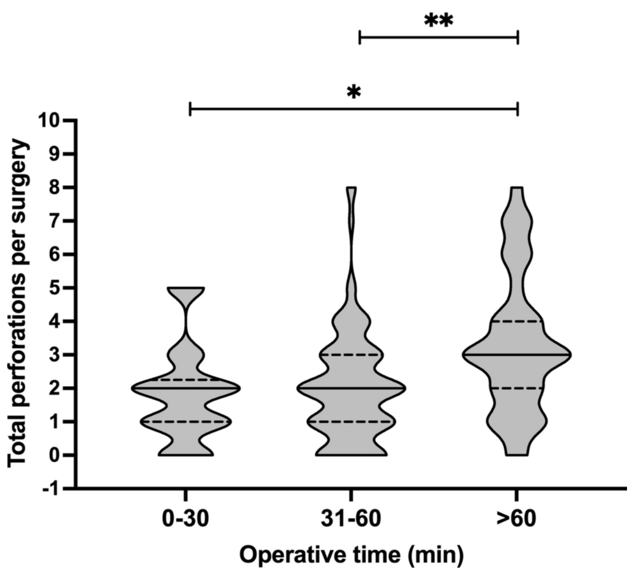

Fig. 4. Perforation rate in relation to operating time. Total perforation rate per surgery analyzed in different groups depending on the operating time. Count of perforations per surgery is given in the y-axis and operating times grouped in 0–30 min, 31–60 min and longer than 60 min are given on the x-axis. $^{*}p < 0.05$, $^{**}p < 0.005$.

several studies comparing PFNA and Gamma nails for differences in surgical outcome, data on the incidence of glove perforations depending on the type of implanted nail is limited[38]. In this analysis glove perforation rate was similar for PFNA and Gamma nails. As a result, glove perforation should be considered as a relevant surgical risk independently of the type of implant being used during intramedullary nail fixation.

The perforation rates detected in this study are equal to or higher than those previously described for other orthopedic surgical procedures such as total joint arthroplasty or revision arthroplasty[21,22]. Surgeries performed on soft tissue only generally show lower perforation rates[26]. In hand surgery and arthroscopic procedures a perforation rate of 1.5–3.4% is common[19,39]. Surgeries performed exclusively on soft tissue generally require less instrumentation and rarely involve rough handling. On the other hand, emergency surgeries and fracture surgeries often occur in less controlled environments and during late hours.

In this study the level of experience of the surgeon did not influence the incidence of glove perforations. While the number of included gloves in this study was higher, similar studies performed in the setting of trauma surgery have shown comparable results[40]. As mentioned earlier, previous studies have found a positive correlation between the increasing complexity of the instrumentation used and an association of bony procedures with intraoperative glove perforations[26]. The fact that surgeon experience doesn't seem to affect glove perforation occurrence implies that the high incidence in orthopedic and trauma surgery is likely caused by typical maneuvers and the consistent handling of bone in most procedures.

A distinct glove perforation pattern could be identified for each of the surgical team members. The majority of perforations in surgeon's gloves occurred on the left-index finger, followed by the right index finger. For assistants, we observed a similar pattern of perforations. The discovery of the left index finger as the primary area of perforation has been noted in previous studies across various orthopedic surgical procedures[19,26]. In contrast, scrub nurses predominantly experienced perforations on the right hand, specifically on the right thumb (25.3%) and right index finger (19.3%). Furthermore, 7.2% of all perforations among scrub nurses occurred on the palm of the right hand, while in surgeons, this area was affected in only 4.2% of cases. These variances could be attributed to differences in how surgical instruments are grasped and utilized during procedures. In this analysis, we identified maneuvers specific to intertrochanteric nail fixation with the highest risk for glove perforation. Instrumentation of the awl or the proximal locking screw accounted for 33.9% of all detected perforations. Wound closure and tissue preparation were the main cause for perforations not related to surgery-specific steps. Standardization of glove changes at these steps, surgery-specific or not, may lead to reduced undetected glove perforations during intramedullary nailing of intertrochanteric fractures.

A higher perforation rate after longer operating times has been reported in the past[19,36]. In this study as well, surgeries that exceeded an operative time of 60 min had a higher perforation rate compared to shorter procedures. A longer operative time may be an indicator of a more challenging surgical intervention which by nature requires more manipulation and instrumentation. 89.3% of all macroperforations were recognized intraoperatively, and consequently resulted in glove changing. However, the majority of all perforations (80.9%) were microperforations, and hence not detected intraoperatively. Although more perforations were located on the outer glove layer, almost 50% of all inner glove perforations occurred on the same site as their corresponding outer glove. When changing gloves during surgery due to a recognized macroperforation on the outer layer, the inner layer should be screened thoroughly for perforation as well. It may also be beneficial to implement a routine glove change after 60 min or earlier to reduce undetected microperforations.

Glove perforations and operating time have both been associated with SSIs in the past[34,36]. Considering this, and the likelihood of underreporting postoperative SSIs due to the hospital's practice of discharging patients promptly after surgery, SSIs were not documented in this study. It is important to reduce undetected glove injuries and to consecutively lower the risk for potential exposure to pathogens for both, patients and surgical personnel as SSIs remain a common complication after surgery. Carter et al. for example wear a third pair of gloves pair for the sole purpose of setting up the surgical area and remove them right before incision[22].

Both glove removal and pressure during the water fill test could lead to false perforations and could present potentially limiting factors to this study. However, the frequent incidence of inner and outer glove perforations in similar locations, along with role-specific sites of perforation, suggests that these are likely genuine occurrences during surgery.

The surgical procedure of intramedullary nailing involves a less invasive procedure per guidance via fluoroscopy, without open reduction manoeuvres, and with short operative times (mean surgical time among our series: 52 min). This study highlights the high-risk of glove perforation in this type of surgery. Especially certain operative steps, as well as complex surgeries with longer operating times have a high occurrence of intraoperative glove perforations. To improve upon the results of this study, future studies should focus on a broader patient demographic, alternative strategies like reinforced gloves or innovative surgical techniques and the psychological impact of glove perforation on the surgical team. Taking all of this into account, standardized and regular glove changing during intramedullary nailing of intertrochanteric fractures is warranted to decrease the risk of potential septic contamination or even disease transmission for both the surgeon and the patient.

Data availability

The datasets generated and/or analysed during this study are not publicly available due to sensitive patient data but are available from the corresponding author on reasonable request.

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Author contributions

J.S. was involved in literature review, data analysis and interpretation, drafting of the manuscript and critical revision; M.W. and J.S. were involved in conceptualization and study design, literature review, data analysis and interpretation, drafting of the manuscript and critical revision; C.H. was involved in literature review, data acquisition, data anylysis and interpretation, drafting of the manuscript and critical revision, L.A., M.L. and S.H. were involved in data acquisition, and critical revision.

Declarations

Competing interests

The authors declare no competing interests.

Additional information

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